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(54) **INTEGRATED SYSTEM FOR INTRAVASCULAR PLACEMENT OF A CATHETER**

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(56) **References Cited**

U.S. PATENT DOCUMENTS

3,133,244 A 5/1964 Wojtulewicz
3,297,020 A 1/1967 Mathiesen
(Continued)

FOREIGN PATENT DOCUMENTS

AU 642647 11/1990
AU 1860597 B2 6/1999
(Continued)

OTHER PUBLICATIONS

"Ascension to Launch New 3D Guidance™ Tracker at TCT 2006." Press Releases from Ascension website: www.ascension-tech.com/news/press_101106.php, last accessed Dec. 1, 2006.
(Continued)

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(57) **ABSTRACT**

An integrated catheter placement system for accurately placing a catheter within a patient's vasculature is disclosed. In one embodiment, the integrated system comprises a system console, a tip location sensor for temporary placement on the patient's chest, and an ultrasound probe. The tip location sensor senses a magnetic field of a stylet disposed in a lumen of the catheter when the catheter is disposed in the vasculature. The ultrasound probe ultrasonically images a portion of the vasculature prior to intravascular introduction of the catheter. The ultrasound probe includes user input controls for controlling use of the ultrasound probe in an ultrasound mode and use of the tip location sensor in a tip location mode. In another embodiment, ECG signal-based
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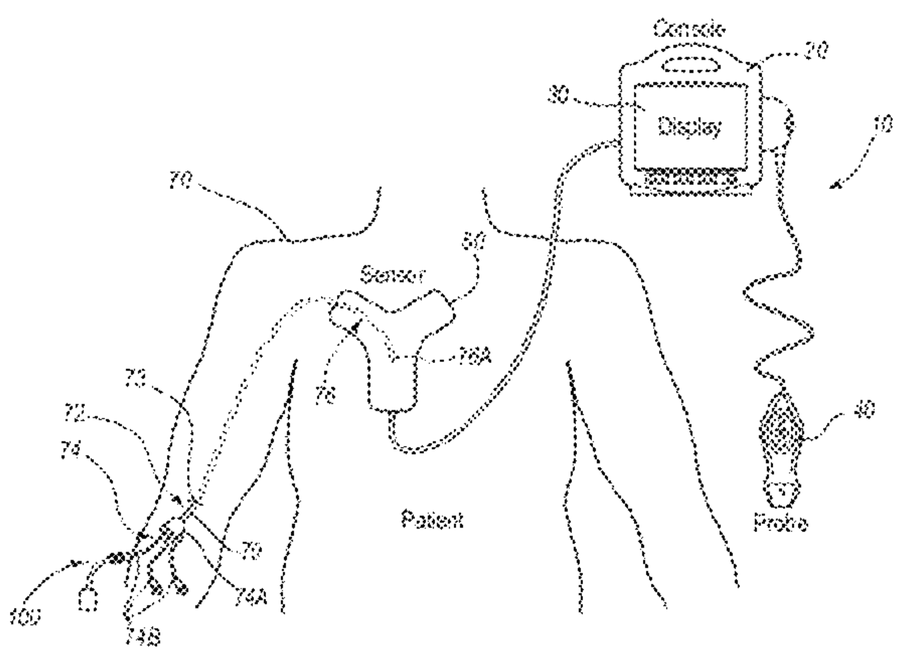

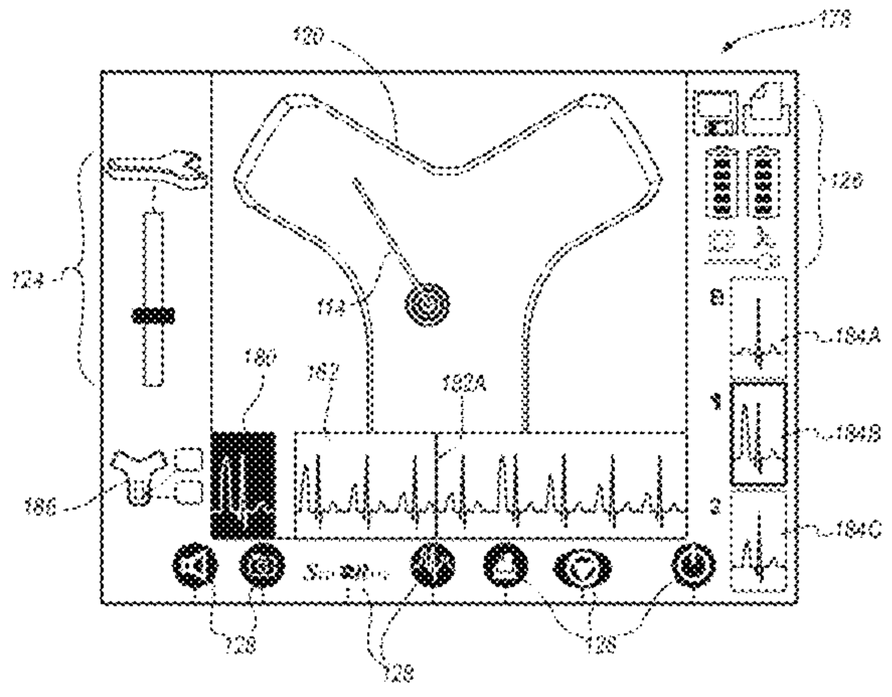

catheter tip guidance is included in the integrated system to enable guidance of the catheter tip to a desired position with respect to a node of the patient's heart.

15 Claims, 14 Drawing Sheets

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,625,200	A	12/1971	Muller
3,674,014	A	7/1972	Tillander et al.
3,817,241	A	6/1974	Grausz
3,847,157	A	11/1974	Caillouette et al.
3,868,565	A	2/1975	Kuipers
3,896,373	A	7/1975	Zelby
3,902,501	A	9/1975	Citron et al.
3,986,373	A	10/1976	Goodlaxson
3,995,623	A	12/1976	Blake et al.
4,003,369	A	1/1977	Heilman et al.
4,063,561	A	12/1977	McKenna
4,072,146	A	2/1978	Howes
4,114,601	A	9/1978	Abels
4,149,535	A	4/1979	Volder et al.
4,173,228	A	11/1979	Van Steenwyk et al.
4,175,566	A	11/1979	Millar
4,181,120	A	1/1980	Kunii et al.
4,224,949	A	9/1980	Scott et al.
4,244,362	A	1/1981	Anderson
4,289,139	A	9/1981	Enjoji et al.
4,317,078	A	2/1982	Weed et al.
4,327,722	A	5/1982	Groshong et al.
4,327,723	A	5/1982	Frankhouser
4,362,166	A	12/1982	Furler et al.
4,365,639	A	12/1982	Goldreyer
4,380,237	A	4/1983	Newbower
4,407,294	A	10/1983	Vilkomerson
4,417,886	A	11/1983	Frankhouser et al.
4,429,693	A	2/1984	Blake et al.
4,431,005	A	2/1984	McCormick
4,431,214	A	2/1984	Buffington
4,445,501	A	5/1984	Bresler
4,459,854	A	7/1984	Richardson et al.
4,469,106	A	9/1984	Harui
4,483,343	A	11/1984	Beyer et al.
4,491,137	A	1/1985	Jingu
4,565,201	A	1/1986	Lass
4,572,198	A	2/1986	Codrington
4,577,634	A	3/1986	Gessman
4,582,067	A	4/1986	Silverstein et al.
4,587,975	A	5/1986	Salo et al.
4,588,394	A	5/1986	Schulte et al.
4,593,687	A	6/1986	Gray
4,595,012	A	6/1986	Webler et al.
4,601,706	A	7/1986	Aillon
4,608,989	A	9/1986	Drue
4,608,992	A	9/1986	Hakim et al.
4,619,247	A	10/1986	Inoue et al.
4,622,644	A	11/1986	Hansen
4,644,960	A	2/1987	Johans
4,652,820	A	3/1987	Maresca
4,660,571	A	4/1987	Hess et al.
4,665,925	A	5/1987	Millar
4,667,230	A	5/1987	Arakawa et al.
4,674,518	A	6/1987	Salo
4,676,249	A	6/1987	Arenas et al.
4,681,106	A	7/1987	Kensey et al.
4,681,117	A	7/1987	Brodman et al.
4,688,578	A	8/1987	Takano et al.
4,692,148	A	9/1987	Kantrowitz et al.
4,697,595	A	10/1987	Breyer et al.
4,700,997	A	10/1987	Strand
4,706,681	A	11/1987	Breyer et al.
4,710,708	A	12/1987	Rorden et al.
4,733,669	A	3/1988	Segal
4,737,794	A	4/1988	Jones
4,741,356	A	5/1988	Letzo et al.
4,742,356	A	5/1988	Kuipers
4,753,247	A	6/1988	Kirsner et al.
4,770,185	A	9/1988	Silverstein et al.
4,771,788	A	9/1988	Millar
4,781,685	A	11/1988	Lehmann et al.
4,784,646	A	11/1988	Feingold
4,787,070	A	11/1988	Suzuki et al.
4,787,396	A	11/1988	Pidorenko
4,790,809	A	12/1988	Kuntz
4,793,361	A	12/1988	DuFault
4,794,930	A	1/1989	Machida et al.
4,796,632	A	1/1989	Boyd et al.
4,798,588	A	1/1989	Aillon
4,798,598	A	1/1989	Bonello et al.
4,809,681	A	3/1989	Kantrowitz et al.
4,809,713	A	3/1989	Grayzel
4,813,729	A	3/1989	Speckhart
4,821,731	A	4/1989	Martinelli et al.
4,836,214	A	6/1989	Sramek
4,840,182	A	6/1989	Carlson
4,840,622	A	6/1989	Hardy
4,841,977	A	6/1989	Griffith et al.
4,849,692	A	7/1989	Blood
4,850,358	A	7/1989	Millar
4,852,580	A	8/1989	Wood
4,856,317	A	8/1989	Pidorenko et al.
4,856,529	A	8/1989	Segal
4,860,757	A	8/1989	Lynch et al.
4,867,169	A	9/1989	Machida et al.
4,869,263	A	9/1989	Segal et al.
4,869,718	A	9/1989	Brader
4,873,987	A	10/1989	Djordjevich et al.
4,887,606	A	12/1989	Yock et al.
4,887,615	A	12/1989	Taylor
4,889,128	A	12/1989	Millar
4,899,756	A	2/1990	Sonek
4,901,725	A	2/1990	Nappholz et al.
4,905,698	A	3/1990	Strohl, Jr. et al.
4,911,173	A	3/1990	Terwilliger
4,911,174	A	3/1990	Pederson et al.
4,917,669	A	4/1990	Bonaldo
4,924,870	A	5/1990	Wlodarczyk et al.
4,943,770	A	7/1990	Ashley-Rollman et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,945,305	A		7/1990	Blood
4,947,852	A		8/1990	Nassi et al.
4,957,110	A		9/1990	Vogel et al.
4,957,111	A		9/1990	Millar
4,961,433	A		10/1990	Christian
4,966,148	A		10/1990	Millar
4,967,753	A		11/1990	Haase et al.
4,977,886	A		12/1990	Takehana et al.
4,989,608	A		2/1991	Ratner
4,989,610	A		2/1991	Patton et al.
4,995,396	A		2/1991	Inaba et al.
4,998,916	A		3/1991	Hammerslag et al.
5,004,456	A		4/1991	Botterbusch et al.
5,005,592	A		4/1991	Cartmell
5,016,173	A		5/1991	Kenet et al.
5,025,799	A		6/1991	Wilson
5,029,585	A		7/1991	Lieber et al.
5,040,548	A		8/1991	Yock
5,042,486	A		8/1991	Pfeiler et al.
5,045,071	A		9/1991	McCormick et al.
5,046,497	A		9/1991	Millar
5,050,607	A		9/1991	Bradley et al.
5,057,095	A		10/1991	Fabian
5,058,583	A		10/1991	Geddes et al.
5,058,595	A		10/1991	Kern
5,067,489	A		11/1991	Lind
5,076,278	A		12/1991	Vilkomerson et al.
5,078,140	A		1/1992	Kwoh
5,078,148	A		1/1992	Nassi et al.
5,078,149	A		1/1992	Katsumata et al.
5,078,678	A	*	1/1992	Katims A61B 5/06 600/547
5,078,714	A		1/1992	Katims
5,084,022	A		1/1992	Claude
5,092,341	A		3/1992	Kelen
5,099,845	A		3/1992	Besz et al.
5,099,850	A		3/1992	Matsui et al.
5,100,387	A		3/1992	Ng
5,105,829	A		4/1992	Fabian et al.
5,109,862	A		5/1992	Kelen et al.
5,114,401	A		5/1992	Stuart et al.
5,121,750	A	*	6/1992	Katims A61B 5/06 600/466
5,125,410	A		6/1992	Misono et al.
5,134,370	A		7/1992	Jefferts et al.
5,144,955	A		9/1992	O'Hara
5,156,151	A	*	10/1992	Imran A61N 1/056 600/375
5,158,086	A		10/1992	Brown et al.
5,160,342	A		11/1992	Reger et al.
5,161,536	A		11/1992	Vilkomerson et al.
5,174,295	A		12/1992	Christian et al.
5,174,299	A		12/1992	Nelson
5,184,601	A		2/1993	Putman
5,190,045	A		3/1993	Frazin
5,202,985	A		4/1993	Goyal
5,205,830	A		4/1993	Dassa et al.
5,211,165	A		5/1993	Dumoulin et al.
5,211,636	A		5/1993	Mische
5,212,988	A		5/1993	White et al.
5,214,615	A		5/1993	Bauer et al.
5,217,026	A		6/1993	Stoy et al.
5,220,924	A		6/1993	Frazin
5,233,994	A		8/1993	Shmulewitz
5,235,987	A		8/1993	Wolfe
5,239,464	A		8/1993	Blair et al.
5,240,004	A		8/1993	Walinsky et al.
5,243,995	A		9/1993	Maier
5,246,007	A		9/1993	Frisbie et al.
5,246,426	A		9/1993	Lewis et al.
5,247,171	A		9/1993	Wlodarczyk et al.
5,251,635	A		10/1993	Dumoulin et al.
5,255,680	A		10/1993	Darrow et al.
5,257,636	A		11/1993	White
5,257,979	A		11/1993	Jagpal
5,261,409	A		11/1993	Dardel
5,265,610	A		11/1993	Darrow et al.
5,265,614	A		11/1993	Hayakawa et al.
5,267,569	A		12/1993	Lienhard
5,270,810	A		12/1993	Nishimura
5,271,404	A		12/1993	Corl et al.
5,273,025	A		12/1993	Sakiyama et al.
5,273,042	A		12/1993	Lynch et al.
5,274,551	A		12/1993	Corby, Jr.
5,275,053	A		1/1994	Wlodarczyk et al.
5,279,129	A		1/1994	Ito
5,279,607	A		1/1994	Schentag et al.
5,280,786	A		1/1994	Wlodarczyk et al.
5,287,331	A		2/1994	Schindel et al.
5,289,373	A		2/1994	Zarge et al.
5,292,342	A		3/1994	Nelson et al.
5,307,072	A		4/1994	Jones, Jr.
5,311,871	A		5/1994	Yock
5,313,949	A		5/1994	Yock
5,318,025	A		6/1994	Dumoulin et al.
5,325,860	A		7/1994	Seward et al.
5,325,873	A		7/1994	Hirschi et al.
5,330,496	A		7/1994	Alferness
5,331,966	A		7/1994	Bennett et al.
5,333,614	A		8/1994	Feiring
5,337,678	A		8/1994	Grout et al.
5,341,807	A		8/1994	Nardella
5,343,865	A		9/1994	Gardineer et al.
5,345,940	A		9/1994	Seward et al.
5,348,020	A		9/1994	Hutson
5,350,352	A		9/1994	Buchholtz et al.
5,357,961	A		10/1994	Fields et al.
5,365,935	A		11/1994	Righter et al.
5,366,443	A		11/1994	Eggers et al.
5,368,048	A		11/1994	Stoy et al.
5,375,596	A		12/1994	Twiss et al.
5,376,083	A		12/1994	Mische
5,377,678	A		1/1995	Dumoulin et al.
5,385,053	A		1/1995	Wlodarczyk et al.
5,385,146	A		1/1995	Goldreyer
5,391,199	A		2/1995	Ben-Haim
5,394,876	A		3/1995	Ma
5,394,877	A		3/1995	Orr et al.
5,395,366	A		3/1995	D'Andrea et al.
5,398,683	A		3/1995	Edwards et al.
5,398,691	A		3/1995	Martin et al.
5,411,485	A		5/1995	Tennican et al.
5,413,107	A		5/1995	Oakley et al.
5,417,208	A		5/1995	Winkler
5,422,478	A		6/1995	Wlodarczyk et al.
5,423,334	A		6/1995	Jordan
5,423,877	A		6/1995	Mackey
5,425,367	A		6/1995	Shapiro et al.
5,425,370	A		6/1995	Vilkomerson
5,425,382	A		6/1995	Golden et al.
5,427,114	A		6/1995	Colliver et al.
5,429,132	A		7/1995	Guy et al.
5,429,617	A		7/1995	Hammersmark et al.
5,431,641	A		7/1995	Grozinger et al.
5,433,729	A		7/1995	Adams et al.
5,437,276	A		8/1995	Takada et al.
5,437,277	A		8/1995	Dumoulin et al.
5,438,873	A		8/1995	Wlodarczyk et al.
5,443,066	A		8/1995	Dumoulin et al.
5,443,489	A		8/1995	Ben-Haim
5,445,150	A		8/1995	Dumoulin et al.
5,445,166	A		8/1995	Taylor
5,450,846	A		9/1995	Goldreyer
5,453,575	A		9/1995	O'Donnell et al.
5,453,576	A		9/1995	Krivitski
5,456,256	A		10/1995	Schneider
5,456,718	A		10/1995	Szymaitis
5,464,016	A		11/1995	Nicholas et al.
5,474,065	A		12/1995	Meathrel et al.
5,476,090	A		12/1995	Kishi
5,480,422	A		1/1996	Ben-Haim
5,487,729	A		1/1996	Avellanet et al.
5,490,522	A		2/1996	Dardel
5,492,538	A		2/1996	Johlin, Jr.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,494,038	A		2/1996	Wang et al.
5,500,011	A		3/1996	Desai
5,500,012	A		3/1996	Brucker et al.
5,505,205	A		4/1996	Solomon et al.
5,509,822	A		4/1996	Negus et al.
5,513,637	A		5/1996	Twiss et al.
5,515,160	A		5/1996	Schulz et al.
5,515,853	A		5/1996	Smith et al.
5,517,989	A	*	5/1996	Frisbie et al. 600/585
5,522,878	A		6/1996	Montecalvo et al.
5,522,880	A		6/1996	Barone et al.
5,526,812	A		6/1996	Dumoulin et al.
5,531,664	A		7/1996	Adachi et al.
5,536,248	A		7/1996	Weaver et al.
5,540,230	A		7/1996	Vilkomerson
5,540,681	A		7/1996	Strul et al.
5,542,938	A		8/1996	Avellanet et al.
5,546,949	A		8/1996	Frazin et al.
5,546,951	A		8/1996	Ben-Haim
5,555,618	A		9/1996	Winkler
5,558,091	A		9/1996	Acker et al.
5,568,809	A		10/1996	Ben-haim
D375,450	S		11/1996	Bidwell et al.
5,570,671	A		11/1996	Hickey
5,575,291	A		11/1996	Hayakawa et al.
5,588,442	A		12/1996	Scovil et al.
5,592,939	A		1/1997	Martinelli
5,598,846	A		2/1997	Peszynski
5,599,299	A		2/1997	Weaver et al.
5,600,330	A		2/1997	Blood
5,603,333	A		2/1997	Konings
5,610,967	A		3/1997	Moorman et al.
5,617,866	A		4/1997	Marian, Jr.
5,622,169	A		4/1997	Golden et al.
5,622,170	A		4/1997	Schulz
5,622,184	A		4/1997	Ashby et al.
5,623,931	A		4/1997	Wung et al.
5,624,430	A		4/1997	Eton et al.
5,626,554	A		5/1997	Ryaby et al.
5,626,870	A		5/1997	Monshipouri et al.
5,630,419	A		5/1997	Ranalletta
5,638,819	A		6/1997	Manwaring et al.
5,644,612	A		7/1997	Moorman et al.
5,645,065	A		7/1997	Shapiro et al.
5,651,047	A		7/1997	Moorman et al.
5,654,864	A		8/1997	Ritter et al.
D383,968	S		9/1997	Bidwell et al.
5,662,115	A		9/1997	Torp et al.
5,665,103	A		9/1997	Lafontaine et al.
5,665,477	A		9/1997	Meathrel et al.
5,666,473	A		9/1997	Wallace
5,666,958	A		9/1997	Rothenberg et al.
5,669,383	A		9/1997	Johnson
5,669,388	A		9/1997	Vilkomerson
5,676,159	A		10/1997	Navis
5,676,673	A		10/1997	Ferre et al.
5,682,890	A		11/1997	Kormos et al.
5,691,898	A		11/1997	Rosenberg et al.
5,694,945	A		12/1997	Ben-Haim
5,695,479	A		12/1997	Jagpal
5,697,377	A		12/1997	Wittkampf
5,699,801	A		12/1997	Atalar et al.
5,700,889	A		12/1997	Blair
5,701,898	A		12/1997	Adam et al.
5,702,433	A		12/1997	Taylor et al.
5,711,299	A		1/1998	Manwaring et al.
5,713,362	A		2/1998	Vilkomerson
5,713,363	A		2/1998	Seward et al.
5,713,858	A		2/1998	Heruth et al.
5,713,946	A		2/1998	Ben-Haim
5,715,817	A		2/1998	Stevens-Wright et al.
5,716,389	A		2/1998	Walinsky et al.
5,718,241	A		2/1998	Ben-Haim et al.
D391,838	S		3/1998	Bidwell et al.
5,722,412	A		3/1998	Pflugrath et al.
5,727,550	A		3/1998	Montecalvo
5,727,552	A		3/1998	Ryan
5,727,553	A		3/1998	Saad
5,729,055	A		3/1998	Manning
5,729,129	A		3/1998	Acker
5,729,584	A		3/1998	Moorman et al.
5,730,129	A		3/1998	Darrow et al.
5,731,996	A		3/1998	Gilbert
5,733,323	A		3/1998	Buck et al.
5,738,096	A		4/1998	Ben-Haim
5,740,808	A		4/1998	Panescu et al.
5,742,394	A		4/1998	Hansen
5,744,953	A		4/1998	Hansen
5,748,767	A		5/1998	Raab
5,749,835	A		5/1998	Glantz
5,749,938	A		5/1998	Coombs
5,751,785	A		5/1998	Moorman et al.
5,752,513	A		5/1998	Acker et al.
5,758,650	A		6/1998	Miller et al.
5,762,064	A		6/1998	Polvani
5,767,669	A		6/1998	Hansen et al.
5,767,960	A		6/1998	Orman et al.
5,769,786	A		6/1998	Wiegel
5,769,843	A		6/1998	Abela et al.
5,769,881	A		6/1998	Schroeppel et al.
5,771,896	A		6/1998	Sliwa, Jr. et al.
5,775,322	A		7/1998	Silverstein et al.
5,775,332	A		7/1998	Goldman
5,776,064	A		7/1998	Kalfas et al.
5,776,080	A		7/1998	Thome et al.
5,779,638	A		7/1998	Vesely et al.
5,782,767	A		7/1998	Pretlow, III
5,782,773	A		7/1998	Kuo et al.
5,785,657	A		7/1998	Breyer et al.
5,792,055	A		8/1998	McKinnon et al.
5,795,297	A		8/1998	Daigle
5,795,298	A	*	8/1998	Vesely A61B 5/0422 600/374
5,795,632	A		8/1998	Buchalter
5,797,849	A		8/1998	Vesely et al.
5,800,352	A		9/1998	Ferre et al.
5,800,410	A		9/1998	Gawreluk
5,800,497	A		9/1998	Bakels et al.
5,803,089	A		9/1998	Ferre et al.
5,810,733	A		9/1998	Van Creveld et al.
RE35,924	E		10/1998	Winkler
5,817,022	A		10/1998	Vesely
5,817,024	A		10/1998	Ogle et al.
5,820,549	A		10/1998	Marian, Jr.
5,824,031	A		10/1998	Cookston et al.
5,827,192	A		10/1998	Gopakumaran et al.
5,829,444	A		11/1998	Ferre et al.
5,830,145	A		11/1998	Tenhoff
5,831,260	A		11/1998	Hansen
5,833,608	A		11/1998	Acker
5,833,622	A		11/1998	Meathrel et al.
5,835,561	A		11/1998	Moorman et al.
5,836,882	A		11/1998	Frazin
5,836,990	A		11/1998	Li
5,840,024	A		11/1998	Taniguchi et al.
5,840,025	A		11/1998	Ben-Haim
5,840,030	A		11/1998	Ferek-Petric et al.
5,840,031	A		11/1998	Crowley
5,842,986	A		12/1998	Avrin et al.
5,842,998	A		12/1998	Gopakumaran et al.
5,843,076	A		12/1998	Webster, Jr. et al.
5,843,153	A		12/1998	Johnston et al.
5,844,140	A		12/1998	Seale
5,846,198	A		12/1998	Killmann
5,855,553	A		1/1999	Tajima et al.
5,859,893	A		1/1999	Moorman et al.
5,865,748	A		2/1999	Co et al.
5,868,673	A		2/1999	Vesely
5,873,822	A		2/1999	Ferre et al.
5,876,328	A		3/1999	Fox et al.
5,879,297	A		3/1999	Haynor et al.
5,893,363	A		4/1999	Little et al.
5,897,495	A		4/1999	Aida et al.
5,899,860	A		5/1999	Pfeiffer et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,902,238	A		5/1999	Golden et al.
5,907,487	A		5/1999	Rosenberg et al.
5,908,385	A		6/1999	Chechelski et al.
5,910,113	A		6/1999	Pruter
5,910,120	A		6/1999	Kim et al.
5,913,820	A		6/1999	Bladen et al.
5,913,830	A		6/1999	Miles
5,919,141	A		7/1999	Money et al.
5,919,170	A		7/1999	Woessner
5,928,145	A		7/1999	Ocali et al.
5,929,607	A		7/1999	Rosenberg et al.
5,931,788	A		8/1999	Keen et al.
5,931,818	A		8/1999	Werp et al.
5,931,863	A	*	8/1999	Griffin et al. 607/122
5,941,858	A		8/1999	Johnson
5,941,889	A		8/1999	Cermak
5,941,904	A		8/1999	Johnston et al.
5,944,022	A		8/1999	Nardella et al.
5,944,023	A		8/1999	Johnson et al.
5,951,598	A		9/1999	Bishay et al.
5,953,683	A		9/1999	Hansen et al.
5,957,857	A		9/1999	Hartley
5,961,923	A		10/1999	Nova et al.
5,967,978	A		10/1999	Littmann et al.
5,967,980	A		10/1999	Ferre et al.
5,967,991	A		10/1999	Gardineer et al.
5,969,722	A		10/1999	Palm
5,971,933	A		10/1999	Gopakumaran et al.
5,978,705	A		11/1999	KenKnight et al.
5,983,126	A		11/1999	Wittkampf
5,984,908	A		11/1999	Davis et al.
5,991,693	A		11/1999	Zalewski
5,997,473	A		12/1999	Taniguchi et al.
5,997,481	A		12/1999	Adams et al.
6,006,123	A		12/1999	Nguyen et al.
6,011,988	A		1/2000	Lynch et al.
6,014,473	A		1/2000	Hossack et al.
6,014,580	A		1/2000	Blume et al.
6,015,414	A		1/2000	Werp et al.
6,017,496	A		1/2000	Nova et al.
6,019,724	A		2/2000	Gronningsaeter et al.
6,019,725	A		2/2000	Vesely et al.
6,022,342	A		2/2000	Mukherjee
6,023,638	A		2/2000	Swanson
6,026,312	A		2/2000	Shemwell et al.
6,031,765	A		2/2000	Lee et al.
6,032,070	A		2/2000	Flock et al.
6,039,694	A		3/2000	Larson et al.
6,050,718	A		4/2000	Schena et al.
6,052,610	A		4/2000	Koch
6,052,618	A		4/2000	Dahlke et al.
D424,693	S		5/2000	Pruter
6,059,718	A		5/2000	Taniguchi et al.
6,064,905	A		5/2000	Webster, Jr. et al.
6,066,094	A		5/2000	Ben-Haim
6,068,599	A		5/2000	Saito et al.
6,073,043	A		6/2000	Schneider
6,074,367	A		6/2000	Hubbell
6,075,442	A		6/2000	Welch
6,076,007	A		6/2000	England et al.
6,081,737	A		6/2000	Shah
6,082,366	A		7/2000	Andra et al.
6,083,170	A		7/2000	Ben-Haim
6,099,524	A		8/2000	Lipson et al.
6,100,026	A		8/2000	Nova et al.
6,102,044	A		8/2000	Naidyhorski
6,107,699	A		8/2000	Swanson
6,112,111	A		8/2000	Glantz
6,112,115	A		8/2000	Feldman et al.
6,113,504	A		9/2000	Kuesters
6,115,624	A		9/2000	Lewis et al.
6,120,445	A		9/2000	Grunwald
6,122,538	A		9/2000	Sliwa, Jr. et al.
6,128,174	A		10/2000	Ritter et al.
6,129,668	A		10/2000	Haynor et al.
6,132,378	A		10/2000	Marino
6,132,379	A		10/2000	Patacsil et al.
6,135,961	A		10/2000	Pflugrath et al.
6,136,274	A		10/2000	Nova et al.
6,138,681	A		10/2000	Chen et al.
6,139,496	A		10/2000	Chen et al.
6,139,502	A		10/2000	Fredriksen
6,139,540	A		10/2000	Rost et al.
6,144,300	A		11/2000	Dames et al.
6,148,823	A		11/2000	Hastings
6,152,933	A		11/2000	Werp et al.
6,157,853	A		12/2000	Blume et al.
6,165,144	A		12/2000	Talish et al.
6,165,977	A		12/2000	Mochly-Rosen
6,166,496	A		12/2000	Lys et al.
6,166,806	A		12/2000	Tjin
6,167,765	B1		1/2001	Weitzel
6,172,499	B1		1/2001	Ashe
6,173,199	B1		1/2001	Gabriel
6,173,715	B1		1/2001	Sinanan et al.
6,175,756	B1		1/2001	Ferre et al.
6,176,829	B1		1/2001	Vilkomerson
6,187,744	B1		2/2001	Rooney
6,190,370	B1		2/2001	Tsui
6,191,136	B1		2/2001	Marban
6,193,743	B1		2/2001	Brayton et al.
6,197,001	B1		3/2001	Wilson et al.
6,200,305	B1		3/2001	Berthiaume et al.
6,203,499	B1		3/2001	Imling et al.
6,208,884	B1		3/2001	Kumar et al.
6,211,626	B1		4/2001	Lys et al.
6,211,666	B1		4/2001	Acker
6,212,426	B1		4/2001	Swanson
6,216,027	B1		4/2001	Willis et al.
6,216,028	B1		4/2001	Haynor et al.
6,216,029	B1		4/2001	Paltieli
6,223,087	B1		4/2001	Williams
6,226,547	B1		5/2001	Lockhart et al.
6,230,042	B1		5/2001	Slettenmark
6,230,046	B1		5/2001	Crane et al.
6,231,518	B1		5/2001	Grabek et al.
6,233,476	B1		5/2001	Strommer et al.
6,233,994	B1		5/2001	Roy et al.
6,236,883	B1		5/2001	Ciaccio et al.
6,238,344	B1		5/2001	Gamelsky et al.
6,241,673	B1		6/2001	Williams
6,246,231	B1		6/2001	Ashe
6,246,898	B1		6/2001	Vesely et al.
6,248,072	B1		6/2001	Murkin
6,248,074	B1		6/2001	Ohno et al.
6,248,075	B1		6/2001	McGee et al.
6,253,770	B1		7/2001	Acker et al.
6,258,035	B1		7/2001	Hoeksel et al.
6,259,941	B1		7/2001	Chia et al.
6,261,231	B1		7/2001	Damphousse et al.
6,263,230	B1		7/2001	Haynor et al.
6,266,550	B1		7/2001	Selmon et al.
6,266,551	B1		7/2001	Osadchy et al.
6,266,552	B1		7/2001	Slettenmark
6,266,563	B1		7/2001	KenKnight et al.
6,270,493	B1		8/2001	Lalonde et al.
6,271,833	B1		8/2001	Rosenberg et al.
6,272,371	B1		8/2001	Shlomo
6,272,374	B1		8/2001	Flock et al.
6,275,258	B1		8/2001	Chim
6,275,724	B1		8/2001	Dickinson et al.
6,277,077	B1		8/2001	Brisken et al.
6,284,459	B1		9/2001	Nova et al.
6,285,898	B1		9/2001	Ben-Haim
6,287,260	B1		9/2001	Hascoet et al.
6,288,704	B1		9/2001	Flack et al.
6,292,678	B1		9/2001	Hall et al.
6,292,680	B1		9/2001	Somogyi et al.
6,292,901	B1		9/2001	Lys et al.
6,293,955	B1		9/2001	Houser et al.
6,296,604	B1		10/2001	Garibaldi et al.
6,298,261	B1		10/2001	Rex
6,304,768	B1		10/2001	Blume et al.
6,306,097	B1		10/2001	Park et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,306,105	B1	10/2001	Rooney et al.
6,311,082	B1	10/2001	Creighton, IV et al.
6,315,709	B1	11/2001	Garibaldi et al.
6,315,727	B1	11/2001	Coleman et al.
6,319,668	B1	11/2001	Nova et al.
6,323,769	B1	11/2001	Dames et al.
6,323,770	B1	11/2001	Dames et al.
6,324,416	B1	11/2001	Seibert
6,325,540	B1	12/2001	Lounsberry et al.
6,325,762	B1	12/2001	Tjin
6,329,139	B1	12/2001	Nova et al.
6,329,916	B1	12/2001	Dames et al.
6,330,467	B1	12/2001	Creighton, IV et al.
6,332,089	B1	12/2001	Acker et al.
6,332,874	B1	12/2001	Eliasen et al.
6,340,588	B1	1/2002	Nova et al.
6,340,868	B1	1/2002	Lys et al.
6,341,231	B1	1/2002	Ferre et al.
6,346,081	B1	2/2002	Vilkomerson
6,348,911	B1	2/2002	Rosenberg et al.
6,350,160	B1	2/2002	Feuersanger et al.
6,352,363	B1	3/2002	Munger et al.
6,354,999	B1	3/2002	Dgany et al.
6,355,026	B1	3/2002	Mick
6,356,791	B1	3/2002	Westlund et al.
6,360,123	B1	3/2002	Kimchi et al.
6,361,499	B1	3/2002	Bates et al.
6,364,823	B1	4/2002	Garibaldi et al.
6,364,839	B1	4/2002	Little et al.
6,366,804	B1	4/2002	Mejia
6,368,285	B1	4/2002	Osadchy et al.
6,370,411	B1	4/2002	Osadchy et al.
6,373,240	B1	4/2002	Govari
6,373,388	B1	4/2002	Dames et al.
6,374,134	B1	4/2002	Bladen et al.
6,374,670	B1	4/2002	Spelman et al.
6,375,606	B1	4/2002	Garibaldi et al.
6,375,639	B1	4/2002	Duplessie et al.
6,377,857	B1	4/2002	Brayton et al.
6,379,302	B1	4/2002	Kessman et al.
6,379,303	B1	4/2002	Seitz et al.
6,379,307	B1	4/2002	Filly et al.
6,381,485	B1	4/2002	Hunter et al.
6,385,472	B1	5/2002	Hall et al.
6,385,476	B1	5/2002	Osadchy et al.
6,398,736	B1	6/2002	Seward
6,398,738	B1	6/2002	Millar
6,401,723	B1	6/2002	Garibaldi et al.
6,406,422	B1	6/2002	Landesberg
6,406,442	B1	6/2002	McFann et al.
6,412,978	B1	7/2002	Watanabe et al.
6,412,980	B1	7/2002	Lounsberry et al.
6,417,839	B1	7/2002	Odell
6,418,332	B1	7/2002	Mastrototaro et al.
6,418,335	B2	7/2002	Avrin et al.
6,423,002	B1	7/2002	Hossack
6,423,050	B1	7/2002	Twardowski
6,427,079	B1	7/2002	Schneider et al.
6,428,551	B1	8/2002	Hall et al.
6,430,315	B1	8/2002	Makram-Ebeid
6,432,069	B1	8/2002	Godo et al.
6,438,411	B1	8/2002	Guttman et al.
6,442,416	B1	8/2002	Schultz
6,445,943	B1	9/2002	Ferre et al.
6,456,874	B1	9/2002	Hafer et al.
6,459,919	B1	10/2002	Lys et al.
6,463,121	B1	10/2002	Milnes
6,466,815	B1	10/2002	Saito et al.
6,471,656	B1	10/2002	Shalman et al.
6,471,658	B1	10/2002	Daniels et al.
6,471,700	B1	10/2002	Burbank et al.
6,473,167	B1	10/2002	Odell
6,474,341	B1	11/2002	Hunter et al.
6,475,152	B1	11/2002	Kelly, Jr. et al.
6,475,223	B1	11/2002	Werp et al.
6,477,402	B1	11/2002	Lynch et al.
6,484,118	B1	11/2002	Govari et al.
6,487,916	B1	12/2002	Gomm et al.
6,491,671	B1	12/2002	Larson, III et al.
6,493,573	B1	12/2002	Martinelli et al.
6,494,832	B1	12/2002	Feldman et al.
6,496,715	B1	12/2002	Lee et al.
6,498,944	B1	12/2002	Ben-Haim et al.
6,500,141	B1	12/2002	Irion et al.
6,505,062	B1	1/2003	Ritter et al.
6,506,159	B2	1/2003	Hascoet et al.
6,507,751	B2	1/2003	Blume et al.
6,508,802	B1	1/2003	Rosengart et al.
6,511,413	B2	1/2003	Landesberg
6,512,958	B1	1/2003	Swoyer et al.
6,514,226	B1	2/2003	Levin et al.
6,514,249	B1	2/2003	Maguire et al.
6,515,657	B1	2/2003	Zanelli
6,516,212	B1	2/2003	Bladen et al.
6,516,231	B1	2/2003	Flammang
6,516,807	B1	2/2003	Panescu et al.
6,517,520	B2	2/2003	Chang et al.
6,522,906	B1	2/2003	Salisbury, Jr. et al.
6,522,907	B1	2/2003	Bladen et al.
6,522,909	B1	2/2003	Garibaldi et al.
6,524,303	B1	2/2003	Garibaldi
6,528,954	B1	3/2003	Lys et al.
6,528,991	B2	3/2003	Ashe
6,529,761	B2	3/2003	Creighton, IV et al.
6,529,766	B1	3/2003	Guendel
6,534,982	B1	3/2003	Jakab
6,535,625	B1	3/2003	Chang et al.
6,537,192	B1	3/2003	Elliott et al.
6,537,196	B1	3/2003	Creighton, IV et al.
6,538,634	B1	3/2003	Chui et al.
6,540,699	B1	4/2003	Smith et al.
6,542,766	B2	4/2003	Hall et al.
6,544,251	B1	4/2003	Crawford
6,545,678	B1	4/2003	Ohazama
6,546,270	B1	4/2003	Goldin et al.
6,546,279	B1	4/2003	Bova et al.
6,546,787	B1	4/2003	Schiller et al.
6,552,841	B1	4/2003	Lasser et al.
6,556,858	B1	4/2003	Zeman
6,562,019	B1	5/2003	Sell
6,564,087	B1	5/2003	Pitris et al.
6,569,101	B2	5/2003	Quistgaard et al.
6,569,103	B2	5/2003	Hoeksel et al.
6,569,160	B1	5/2003	Goldin et al.
6,569,862	B1	5/2003	Marban
6,571,004	B1	5/2003	Florent et al.
6,574,518	B1	6/2003	Lounsberry et al.
6,575,908	B2	6/2003	Barnes et al.
6,577,080	B2	6/2003	Lys et al.
6,577,896	B2	6/2003	Werner et al.
6,584,343	B1	6/2003	Ransbury et al.
6,593,754	B1	7/2003	Steber et al.
6,593,884	B1	7/2003	Gilboa et al.
6,597,943	B2	7/2003	Taha et al.
6,599,249	B1	7/2003	Nordgren et al.
6,607,488	B1	8/2003	Jackson et al.
6,610,058	B2	8/2003	Flores
6,611,141	B1	8/2003	Schulz et al.
6,615,071	B1	9/2003	Casscells, III et al.
6,615,155	B2	9/2003	Gilboa
6,616,610	B2	9/2003	Steininger et al.
6,618,612	B1	9/2003	Acker et al.
6,626,832	B1	9/2003	Paltieli et al.
6,626,834	B2	9/2003	Dunne et al.
6,626,902	B1	9/2003	Kucharczyk et al.
6,630,879	B1	10/2003	Creighton, IV et al.
6,635,027	B1	10/2003	Cragg et al.
6,645,148	B2	11/2003	Nguyen-Dinh et al.
6,648,875	B2	11/2003	Simpson et al.
6,649,914	B1	11/2003	Moorman et al.
6,652,505	B1	11/2003	Tsugita
6,652,506	B2	11/2003	Bowe et al.
6,660,024	B1	12/2003	Flaherty et al.
6,662,034	B2	12/2003	Segner et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,663,661	B2	12/2003	Boneau	
6,666,828	B2	12/2003	Greco et al.	
6,672,308	B1	1/2004	Gaspari	
6,677,752	B1	1/2004	Creighton, IV et al.	
6,679,857	B1	1/2004	Bastia et al.	
6,684,176	B2	1/2004	Willins et al.	
6,685,644	B2	2/2004	Seo	
6,687,531	B1	2/2004	Ferre et al.	
6,689,119	B1 *	2/2004	Di Caprio et al.	604/523
6,690,963	B2	2/2004	Ben-Haim et al.	
6,690,964	B2	2/2004	Bieger et al.	
6,690,968	B2	2/2004	Mejia	
6,694,167	B1	2/2004	Ferre et al.	
6,695,786	B2	2/2004	Wang et al.	
6,701,179	B1	3/2004	Martinelli et al.	
6,701,918	B2	3/2004	Fariss et al.	
6,702,804	B1	3/2004	Ritter et al.	
6,704,590	B2	3/2004	Haldeman	
6,709,390	B1	3/2004	Marie Pop	
6,711,429	B1	3/2004	Gilboa et al.	
6,711,431	B2	3/2004	Sarin et al.	
6,719,699	B2	4/2004	Smith	
6,719,724	B1	4/2004	Walker et al.	
6,719,756	B1	4/2004	Muntermann	
6,720,745	B2	4/2004	Lys et al.	
6,733,458	B1	5/2004	Steins et al.	
6,733,511	B2	5/2004	Hall et al.	
6,736,782	B2	5/2004	Pfeiffer et al.	
6,738,656	B1	5/2004	Ferre et al.	
6,740,103	B2	5/2004	Hall et al.	
6,743,177	B2	6/2004	Ito et al.	
6,754,596	B2	6/2004	Ashe	
6,755,789	B2	6/2004	Stringer et al.	
6,755,816	B2	6/2004	Ritter et al.	
6,755,822	B2	6/2004	Reu et al.	
6,757,557	B1	6/2004	Bladen et al.	
6,763,261	B2	7/2004	Casscells, III et al.	
6,764,449	B2	7/2004	Lee et al.	
6,768,496	B2	7/2004	Bieger et al.	
6,772,001	B2	8/2004	Maschke et al.	
6,774,624	B2	8/2004	Anderson et al.	
6,783,536	B2	8/2004	Vilsmeier et al.	
6,784,660	B2	8/2004	Ashe	
6,785,571	B2	8/2004	Glossop et al.	
6,786,219	B2	9/2004	Garibaldi et al.	
6,786,870	B2	9/2004	Miyaki et al.	
6,788,967	B2	9/2004	Ben-Haim et al.	
6,794,667	B2	9/2004	Noshi	
6,799,066	B2	9/2004	Steines et al.	
6,815,651	B2	11/2004	Odell	
6,816,266	B2	11/2004	Varshneya et al.	
6,817,364	B2	11/2004	Garibaldi	
6,834,201	B2	12/2004	Gillies et al.	
6,844,713	B2	1/2005	Steber et al.	
6,845,142	B2	1/2005	Ohishi	
6,856,823	B2	2/2005	Ashe	
6,860,422	B2	3/2005	Hull et al.	
6,862,467	B2	3/2005	Moore et al.	
6,869,390	B2	3/2005	Elliott et al.	
6,875,179	B2	4/2005	Ferguson et al.	
6,879,160	B2	4/2005	Jakab	
6,887,206	B2	5/2005	Hoeksel et al.	
6,889,091	B2	5/2005	Hine et al.	
6,895,268	B1	5/2005	Rahn et al.	
6,902,528	B1	6/2005	Garibaldi et al.	
6,905,469	B2	6/2005	Hascoet et al.	
6,908,433	B1	6/2005	Pruter	
6,911,026	B1	6/2005	Hall et al.	
6,923,782	B2	8/2005	O'Mahony et al.	
6,926,673	B2	8/2005	Roberts et al.	
6,926,674	B2	8/2005	Tenerz et al.	
6,934,575	B2	8/2005	Ferre et al.	
6,936,010	B2	8/2005	Fang et al.	
6,939,313	B2	9/2005	Saadat et al.	
6,940,379	B2	9/2005	Creighton	
6,941,166	B2	9/2005	MacAdam et al.	
6,947,788	B2	9/2005	Gilboa et al.	
6,950,689	B1	9/2005	Willis et al.	
6,953,754	B2	10/2005	Machida et al.	
6,958,677	B1	10/2005	Carter	
6,959,214	B2	10/2005	Pape et al.	
6,962,566	B2	11/2005	Quistgaard et al.	
6,968,846	B2	11/2005	Viswanathan	
6,975,197	B2	12/2005	Creighton, IV	
6,976,962	B2	12/2005	Bullis	
6,976,987	B2	12/2005	Flores	
6,980,843	B2	12/2005	Eng et al.	
6,980,852	B2	12/2005	Jersey-Willuhn et al.	
6,980,921	B2	12/2005	Anderson et al.	
6,986,739	B2	1/2006	Warren et al.	
6,986,744	B1	1/2006	Krivitski	
6,999,821	B2	2/2006	Jenney et al.	
7,001,355	B2	2/2006	Nunomura et al.	
7,008,418	B2	3/2006	Hall et al.	
7,010,338	B2	3/2006	Ritter et al.	
7,015,393	B2	3/2006	Weiner et al.	
7,017,584	B2	3/2006	Garibaldi et al.	
7,019,610	B2	3/2006	Creighton, IV et al.	
7,020,512	B2	3/2006	Ritter et al.	
D518,574	S	4/2006	Chaggares	
7,022,075	B2	4/2006	Grunwald et al.	
7,022,082	B2	4/2006	Sonek	
7,026,927	B2	4/2006	Wright et al.	
7,027,634	B2	4/2006	Odell	
7,028,387	B1	4/2006	Huynh et al.	
7,029,446	B2	4/2006	Wendelken et al.	
7,033,603	B2	4/2006	Nelson et al.	
D520,139	S	5/2006	Chaggares	
D520,140	S	5/2006	Chaggares	
7,038,398	B1	5/2006	Lys et al.	
7,038,657	B2	5/2006	Rosenberg et al.	
7,043,293	B1	5/2006	Baura	
7,048,733	B2	5/2006	Hartley et al.	
7,054,228	B1	5/2006	Hickling	
7,065,403	B1	6/2006	Mouchawar et al.	
7,066,914	B2	6/2006	Andersen	
7,066,924	B1	6/2006	Garibaldi et al.	
7,069,072	B2	6/2006	Jansen et al.	
D525,363	S	7/2006	Chaggares	
7,070,565	B2	7/2006	Vaezy et al.	
7,072,704	B2	7/2006	Bucholz	
7,082,325	B2	7/2006	Hashimshony et al.	
7,090,639	B2	8/2006	Govari	
7,096,059	B2	8/2006	Geddes et al.	
7,096,148	B2	8/2006	Anderson et al.	
7,096,870	B2	8/2006	Lamprich et al.	
7,098,907	B2	8/2006	Houston et al.	
7,103,205	B2	9/2006	Wang et al.	
7,104,980	B1	9/2006	Laherty et al.	
7,106,043	B1	9/2006	Da Silva et al.	
7,106,431	B2	9/2006	Odell	
7,106,479	B2	9/2006	Roy et al.	
7,107,105	B2	9/2006	Bjorklund et al.	
7,112,197	B2	9/2006	Hartley et al.	
7,128,734	B1	10/2006	Wilson et al.	
7,132,804	B2	11/2006	Lys et al.	
7,137,976	B2	11/2006	Ritter et al.	
7,141,019	B2	11/2006	Pearlman	
7,141,812	B2	11/2006	Appleby et al.	
7,142,905	B2	11/2006	Slayton et al.	
7,148,970	B2	12/2006	de Boer	
7,153,291	B2	12/2006	Bierman	
7,161,453	B2	1/2007	Creighton, IV	
7,162,291	B1	1/2007	Nachaliel	
7,167,738	B2	1/2007	Schweikard et al.	
7,169,107	B2	1/2007	Jersey-Willuhn et al.	
7,169,109	B2	1/2007	Jansen et al.	
7,174,201	B2	2/2007	Govari et al.	
7,175,646	B2	2/2007	Brenneman et al.	
7,180,252	B2	2/2007	Lys et al.	
7,184,820	B2	2/2007	Jersey-Willuhn et al.	
7,189,198	B2	3/2007	Harburn et al.	
7,189,205	B2	3/2007	McMorrow et al.	
7,189,208	B1	3/2007	Beatty et al.	

(56) **References Cited**

U.S. PATENT DOCUMENTS

7,190,819	B2	3/2007	Viswanathan	
7,194,295	B2	3/2007	Vilsmeier	
7,204,798	B2	4/2007	Zdeblick et al.	
7,206,064	B2	4/2007	Rogers et al.	
7,207,941	B2	4/2007	Sharf	
7,211,082	B2	5/2007	Hall et al.	
7,214,191	B2	5/2007	Stringer et al.	
7,215,326	B2	5/2007	Rosenberg	
7,221,104	B2	5/2007	Lys et al.	
7,223,256	B2	5/2007	Bierman	
7,229,400	B2	6/2007	Elliott et al.	
7,231,243	B2	6/2007	Tearney et al.	
7,236,157	B2	6/2007	Schena et al.	
7,236,816	B2	6/2007	Kumar et al.	
7,236,820	B2	6/2007	Mabary et al.	
7,237,313	B2	7/2007	Skujins et al.	
7,241,267	B2	7/2007	Furia	
7,244,234	B2	7/2007	Ridley et al.	
7,248,032	B1	7/2007	Hular et al.	
7,248,914	B2	7/2007	Hastings et al.	
7,252,633	B2	8/2007	Obata et al.	
7,264,584	B2	9/2007	Ritter et al.	
7,270,662	B2	9/2007	Visram et al.	
7,276,044	B2	10/2007	Ferry et al.	
7,286,034	B2	10/2007	Creighton	
7,291,146	B2	11/2007	Steinke et al.	
7,297,140	B2	11/2007	Orlu et al.	
7,300,430	B2	11/2007	Wilson et al.	
7,302,288	B1	11/2007	Schellenberg	
7,308,296	B2	12/2007	Lys et al.	
7,310,150	B2	12/2007	Guillermo et al.	
7,311,702	B2	12/2007	Tallarida et al.	
7,321,228	B2	1/2008	Govari	
7,326,241	B2	2/2008	Jang	
7,327,872	B2	2/2008	Vaillant et al.	
7,342,058	B2	3/2008	Peppmoller et al.	
7,349,732	B1	3/2008	Kil et al.	
7,355,716	B2	4/2008	de Boer et al.	
7,360,427	B2	4/2008	Drinkwater et al.	
7,366,376	B2	4/2008	Shishkov et al.	
7,366,562	B2	4/2008	Dukesherer et al.	
7,366,563	B2	4/2008	Kleen et al.	
7,373,271	B1	5/2008	Schneider	
7,381,204	B2	6/2008	Wilson et al.	
7,382,949	B2	6/2008	Bouma et al.	
7,384,407	B2	6/2008	Rodriguez et al.	
7,418,169	B2	8/2008	Tearney et al.	
7,447,408	B2	11/2008	Bouma et al.	
7,452,331	B1	11/2008	Pruter	
7,452,358	B2	11/2008	Stern et al.	
7,454,244	B2	11/2008	Kassab et al.	
D585,556	S	1/2009	Kosaku	
7,479,141	B2	1/2009	Kleen et al.	
7,519,424	B2	4/2009	Dennis et al.	
7,529,584	B2	5/2009	Laske et al.	
7,534,223	B2	5/2009	Boutilette et al.	
7,538,859	B2	5/2009	Tearney et al.	
7,543,239	B2	6/2009	Viswanathan et al.	
7,546,158	B2	6/2009	Allison et al.	
7,547,282	B2	6/2009	Lo et al.	
7,551,293	B2	6/2009	Yelin et al.	
D603,050	S	10/2009	Chen	
7,599,730	B2	10/2009	Hunter et al.	
7,606,615	B2	10/2009	Makower et al.	
7,616,992	B2	11/2009	Dennis et al.	
7,627,376	B2	12/2009	Dennis et al.	
7,635,336	B1	12/2009	Pruter	
7,637,163	B2	12/2009	Fetzer et al.	
7,640,053	B2	12/2009	Verin	
7,651,469	B2	1/2010	Osborne et al.	
7,652,080	B2	1/2010	Peppmoller et al.	
7,660,623	B2	2/2010	Hunter et al.	
7,665,893	B2	2/2010	Buchalter	
7,668,583	B2	2/2010	Fegert et al.	
7,697,972	B2	4/2010	Verard et al.	
7,699,782	B2	4/2010	Angelsen et al.	
7,699,829	B2	4/2010	Harris et al.	
7,715,925	B2	5/2010	Hafer et al.	
7,727,192	B2	6/2010	Tokumoto et al.	
7,729,743	B2	6/2010	Sabczynski et al.	
7,751,865	B2	7/2010	Jascob et al.	
7,766,839	B2	8/2010	Rogers et al.	
7,771,437	B2	8/2010	Hogg et al.	
7,774,051	B2	8/2010	Voth	
7,774,055	B1	8/2010	Min	
7,794,407	B2	9/2010	Rothenberg	
7,798,970	B2	9/2010	Lo et al.	
7,819,810	B2	10/2010	Stringer et al.	
7,828,528	B2 *	11/2010	Estes	A61M 5/14244 417/43
7,831,294	B2	11/2010	Viswanathan	
7,833,168	B2	11/2010	Taylor et al.	
7,833,214	B2	11/2010	Wilson et al.	
D629,526	S	12/2010	Ladwig et al.	
D629,527	S	12/2010	Crunkilton	
7,846,157	B2	12/2010	Kozel	
7,850,613	B2	12/2010	Stribling	
D630,756	S	1/2011	Kitayama	
D630,757	S	1/2011	Kitayama	
7,869,854	B2	1/2011	Shachar et al.	
7,873,402	B2	1/2011	Shachar	
7,909,815	B2	3/2011	Whitmore, III et al.	
7,931,596	B2	4/2011	Rachlin et al.	
7,947,040	B2	5/2011	Davies et al.	
7,976,469	B2	7/2011	Bonde et al.	
7,976,518	B2 *	7/2011	Shaughnessy et al.	604/284
7,981,038	B2	7/2011	Kanade et al.	
7,988,633	B2	8/2011	Hossack et al.	
8,016,814	B2	9/2011	Blakstvedt et al.	
8,046,052	B2	10/2011	Verard et al.	
8,057,394	B2	11/2011	Dala-Krishna	
8,060,185	B2	11/2011	Hunter et al.	
8,078,274	B2	12/2011	Kassab	
8,078,279	B2	12/2011	Dennis et al.	
8,082,032	B2	12/2011	Kassab et al.	
8,088,072	B2	1/2012	Munrow et al.	
8,090,430	B2	1/2012	Makower et al.	
8,099,161	B2	1/2012	Kassab	
8,114,143	B2	2/2012	Kassab et al.	
8,118,743	B2	2/2012	Park et al.	
8,123,691	B2	2/2012	Mine et al.	
8,133,698	B2	3/2012	Silver	
8,142,417	B2	3/2012	Pajunk et al.	
8,150,522	B2	4/2012	Echauz et al.	
8,152,724	B2	4/2012	Ridley et al.	
8,204,582	B2	6/2012	Zantos et al.	
8,214,018	B2	7/2012	Markowitz et al.	
8,221,402	B2	7/2012	Francischelli et al.	
8,240,211	B2	8/2012	Zeitner et al.	
8,241,274	B2	8/2012	Keogh et al.	
8,244,339	B2	8/2012	Shen et al.	
8,255,035	B2	8/2012	Cao et al.	
8,260,395	B2	9/2012	Markowitz et al.	
8,262,577	B2	9/2012	Munrow et al.	
8,298,149	B2	10/2012	Hastings et al.	
8,303,502	B2	11/2012	Washburn et al.	
8,303,505	B2	11/2012	Webler et al.	
8,326,419	B2	12/2012	Rosenberg et al.	
8,340,751	B2	12/2012	Markowitz et al.	
8,369,922	B2	2/2013	Paul et al.	
8,388,541	B2	3/2013	Messerly et al.	
8,388,546	B2	3/2013	Rothenberg	
8,391,956	B2	3/2013	Zellers et al.	
8,401,616	B2	3/2013	Verard et al.	
8,409,103	B2	4/2013	Grunwald et al.	
8,425,425	B2	4/2013	Hagy et al.	
8,437,833	B2	5/2013	Silverstein	
8,439,873	B1	5/2013	Donovan	
8,442,621	B2	5/2013	Gorek et al.	
8,447,384	B2	5/2013	Xu et al.	
D684,265	S	6/2013	Cadera	
8,456,182	B2	6/2013	Bar-Tal et al.	
8,478,382	B2	7/2013	Burnside et al.	
8,485,980	B2	7/2013	Sinderby et al.	

(56) **References Cited**

U.S. PATENT DOCUMENTS

8,494,608	B2	7/2013	Markowitz et al.	
8,496,592	B2	7/2013	Ridley et al.	
8,504,139	B2	8/2013	Jacobsen et al.	
8,512,256	B2	8/2013	Rothenberg	
8,527,036	B2	9/2013	Jalde et al.	
8,538,509	B2	9/2013	Harlev et al.	
8,644,907	B2	2/2014	Hartmann et al.	
8,734,440	B2	5/2014	Wu	
8,774,907	B2	7/2014	Rothenberg	
8,781,555	B2	7/2014	Burnside et al.	
8,784,336	B2	7/2014	Bown et al.	
8,801,693	B2 *	8/2014	He	A61B 5/068 600/327
8,849,382	B2	9/2014	Cox et al.	
8,858,455	B2	10/2014	Rothenberg	
8,934,961	B2	1/2015	Lakin et al.	
8,971,994	B2	3/2015	Burnside et al.	
9,125,578	B2	9/2015	Grunwald	
9,339,206	B2	5/2016	Grunwald	
9,456,766	B2	10/2016	Cox et al.	
9,492,097	B2	11/2016	Wilkes et al.	
9,521,961	B2	12/2016	Silverstein et al.	
9,526,440	B2	12/2016	Burnside et al.	
9,532,724	B2	1/2017	Grunwald	
9,554,716	B2	1/2017	Burnside et al.	
2002/0010392	A1	1/2002	Desai	
2002/0016549	A1	2/2002	Mejia	
2002/0019447	A1	2/2002	Renn et al.	
2002/0022777	A1	2/2002	Crieghton et al.	
2002/0032391	A1	3/2002	McFann et al.	
2002/0049488	A1	4/2002	Boneau	
2002/0055680	A1	5/2002	Miele et al.	
2002/0082559	A1	6/2002	Chang et al.	
2002/0113555	A1	8/2002	Lys et al.	
2002/0123679	A1	9/2002	Dominguez	
2002/0128554	A1	9/2002	Seward	
2002/0129952	A1	9/2002	Matsudate et al.	
2002/0133079	A1	9/2002	Sandhu	
2002/0156363	A1	10/2002	Hunter et al.	
2002/0156376	A1	10/2002	Wang et al.	
2002/0165448	A1	11/2002	Ben-Haim et al.	
2002/0165534	A1	11/2002	Hayzelden et al.	
2002/0165537	A1	11/2002	Kelley et al.	
2002/0198568	A1	12/2002	Hafer et al.	
2003/0009132	A1	1/2003	Schwartz et al.	
2003/0011359	A1	1/2003	Ashe	
2003/0013966	A1	1/2003	Barnes et al.	
2003/0013986	A1	1/2003	Saadat	
2003/0018251	A1	1/2003	Solomon	
2003/0036696	A1	2/2003	Willis et al.	
2003/0040671	A1	2/2003	Somogyi et al.	
2003/0040743	A1	2/2003	Cosman et al.	
2003/0072805	A1	4/2003	Miyazawa et al.	
2003/0073901	A1	4/2003	Simon et al.	
2003/0076281	A1	4/2003	Morgan et al.	
2003/0083698	A1	5/2003	Whitehurst et al.	
2003/0088195	A1	5/2003	Vardi et al.	
2003/0100849	A1	5/2003	Jang	
2003/0114742	A1	6/2003	Lewkowicz et al.	
2003/0114777	A1	6/2003	Griffin et al.	
2003/0120150	A1	6/2003	Govari	
2003/0120154	A1	6/2003	Sauer et al.	
2003/0139661	A1	7/2003	Kimchy et al.	
2003/0149328	A1	8/2003	Elliott et al.	
2003/0149368	A1	8/2003	Hennemann et al.	
2003/0152290	A1	8/2003	Odell	
2003/0160721	A1	8/2003	Gilboa et al.	
2003/0163037	A1	8/2003	Bladen et al.	
2003/0163142	A1	8/2003	Paltieli et al.	
2003/0171691	A1	9/2003	Casscells et al.	
2003/0173953	A1	9/2003	Ashe	
2003/0181892	A1	9/2003	Pajunk et al.	
2003/0184544	A1	10/2003	Prudent	
2003/0191392	A1	10/2003	Haldeman	
2003/0191460	A1	10/2003	Hobbs et al.	
2003/0195420	A1	10/2003	Mendlein et al.	
2003/0199746	A1	10/2003	Fuimaono et al.	
2003/0208142	A1	11/2003	Boudewijn et al.	
2003/0216639	A1	11/2003	Gilboa et al.	
2003/0220557	A1	11/2003	Cleary et al.	
2003/0220578	A1	11/2003	Ho et al.	
2003/0229298	A1	12/2003	Iwami et al.	
2003/0233042	A1	12/2003	Ashe	
2003/0236445	A1	12/2003	Couvillon	
2004/0010189	A1	1/2004	van Sloun et al.	
2004/0015070	A1	1/2004	Liang et al.	
2004/0024301	A1	2/2004	Hockett et al.	
2004/0030319	A1	2/2004	Korkor et al.	
2004/0054278	A1	3/2004	Kimchy et al.	
2004/0059237	A1	3/2004	Narayan et al.	
2004/0082916	A1	4/2004	Jenkins	
2004/0087877	A1	5/2004	Besz et al.	
2004/0088136	A1	5/2004	Ashe	
2004/0092962	A1	5/2004	Thornton et al.	
2004/0097803	A1	5/2004	Panescu	
2004/0097804	A1	5/2004	Sobe	
2004/0097805	A1 *	5/2004	Verard et al.	600/428
2004/0097806	A1	5/2004	Hunter et al.	
2004/0116809	A1	6/2004	Chow et al.	
2004/0127805	A1	7/2004	MacAdam et al.	
2004/0131998	A1	7/2004	Marom et al.	
2004/0133111	A1	7/2004	Szczech et al.	
2004/0133130	A1	7/2004	Ferry et al.	
2004/0135069	A1	7/2004	Odell	
2004/0138557	A1	7/2004	Le et al.	
2004/0138564	A1	7/2004	Hwang et al.	
2004/0138570	A1	7/2004	Nita et al.	
2004/0147837	A1	7/2004	Macaulay et al.	
2004/0150963	A1	8/2004	Holmberg et al.	
2004/0152972	A1	8/2004	Hunter	
2004/0155609	A1	8/2004	Lys et al.	
2004/0158140	A1	8/2004	Fuimaono et al.	
2004/0171924	A1	9/2004	Mire et al.	
2004/0176688	A1	9/2004	Haldeman	
2004/0186461	A1	9/2004	DiMatteo	
2004/0199069	A1	10/2004	Connelly et al.	
2004/0210289	A1	10/2004	Wang et al.	
2004/0225233	A1	11/2004	Frankowski et al.	
2004/0230131	A1	11/2004	Kassab et al.	
2004/0230271	A1	11/2004	Wang et al.	
2004/0234453	A1	11/2004	Smith	
2004/0243018	A1	12/2004	Organ et al.	
2004/0243116	A1	12/2004	Joye et al.	
2004/0243118	A1	12/2004	Ayers et al.	
2004/0253365	A1	12/2004	Warren et al.	
2004/0254470	A1	12/2004	Drinkwater et al.	
2004/0254495	A1	12/2004	Mabary et al.	
2004/0260174	A1	12/2004	Keene	
2004/0267086	A1	12/2004	Anstadt et al.	
2005/0004450	A1	1/2005	Ben-Haim et al.	
2005/0021019	A1	1/2005	Hashimshony et al.	
2005/0033150	A1	2/2005	Takahashi et al.	
2005/0038355	A1	2/2005	Gellman et al.	
2005/0043640	A1	2/2005	Chang	
2005/0049486	A1	3/2005	Urquhart et al.	
2005/0049510	A1	3/2005	Haldeman et al.	
2005/0063194	A1	3/2005	Lys et al.	
2005/0070788	A1	3/2005	Wilson et al.	
2005/0075561	A1	4/2005	Golden	
2005/0085716	A1	4/2005	Hamm et al.	
2005/0085718	A1	4/2005	Shahidi	
2005/0085720	A1	4/2005	Jascob et al.	
2005/0090746	A1	4/2005	Ohtake	
2005/0096543	A1 *	5/2005	Jackson	A61B 8/488 600/441
2005/0101868	A1	5/2005	Ridley et al.	
2005/0101869	A1	5/2005	Burba et al.	
2005/0105081	A1	5/2005	Odell	
2005/0105101	A1	5/2005	Duling et al.	
2005/0112135	A1	5/2005	Cormier et al.	
2005/0113669	A1	5/2005	Helfer et al.	
2005/0113676	A1	5/2005	Weiner et al.	
2005/0113700	A1	5/2005	Yanagihara et al.	
2005/0113873	A1	5/2005	Weiner et al.	

(56) **References Cited**

U.S. PATENT DOCUMENTS

2005/0113874 A1 5/2005 Connelly et al.
2005/0113876 A1 5/2005 Weiner et al.
2005/0148836 A1 7/2005 Kleen et al.
2005/0148902 A1 7/2005 Minar et al.
2005/0149002 A1 7/2005 Wang et al.
2005/0151489 A1 7/2005 Lys et al.
2005/0154308 A1 7/2005 Quistgaard et al.
2005/0159644 A1 7/2005 Takano
2005/0159790 A1 7/2005 Shalev
2005/0165301 A1 7/2005 Smith et al.
2005/0165313 A1 7/2005 Byron et al.
2005/0175665 A1 8/2005 Hunter et al.
2005/0175703 A1 8/2005 Hunter et al.
2005/0178395 A1 8/2005 Hunter et al.
2005/0178396 A1 8/2005 Hunter et al.
2005/0182295 A1 8/2005 Soper et al.
2005/0182454 A1 8/2005 Gharib et al.
2005/0197674 A1 9/2005 McCabe et al.
2005/0203368 A1 9/2005 Verin
2005/0203396 A1 9/2005 Angelsen et al.
2005/0205081 A1 9/2005 Barker et al.
2005/0215901 A1 9/2005 Anderson et al.
2005/0215945 A1 9/2005 Harris et al.
2005/0222532 A1 10/2005 Bertolero et al.
2005/0240102 A1 10/2005 Rachlin et al.
2005/0245811 A1 11/2005 Scheffler
2005/0256398 A1 11/2005 Hastings et al.
2005/0256451 A1 11/2005 Adams et al.
2005/0256521 A1 11/2005 Kozel
2005/0256541 A1 11/2005 Stypulkowski
2005/0283210 A1 12/2005 Blischak et al.
2005/0283216 A1 12/2005 Pyles
2005/0288586 A1 12/2005 Ferek-Petric
2006/0009759 A1 1/2006 Chrisitian et al.
2006/0015003 A1 1/2006 Moaddes et al.
2006/0025677 A1 2/2006 Verard et al.
2006/0025697 A1 2/2006 Kurzweil et al.
2006/0058633 A1 3/2006 Hoshino et al.
2006/0068074 A1 3/2006 Stefandl
2006/0084867 A1 4/2006 Tremblay et al.
2006/0106306 A1 5/2006 Essner et al.
2006/0116571 A1 6/2006 Maschke et al.
2006/0116576 A1 6/2006 McGee et al.
2006/0116578 A1 6/2006 Grunwald et al.
2006/0122514 A1 6/2006 Byrd et al.
2006/0142656 A1 6/2006 Malackowski et al.
2006/0149134 A1 7/2006 Soper et al.
2006/0173251 A1 8/2006 Govari et al.
2006/0173329 A1 8/2006 Irioka et al.
2006/0173407 A1 8/2006 Shaughnessy et al.
2006/0176242 A1 8/2006 Jaramaz et al.
2006/0184074 A1 8/2006 Vaezy et al.
2006/0206037 A1 9/2006 Braxton
2006/0211944 A1 9/2006 Mauge et al.
2006/0217655 A1 9/2006 Vitullo et al.
2006/0224188 A1 10/2006 Libbus et al.
2006/0247746 A1 11/2006 Danek et al.
2006/0258895 A1 11/2006 Maschke
2006/0276867 A1 12/2006 Viswanathan
2007/0010753 A1 1/2007 MacAdam
2007/0016007 A1 1/2007 Govari et al.
2007/0016013 A1 1/2007 Camus
2007/0016068 A1 1/2007 Grunwald et al.
2007/0016069 A1 1/2007 Grunwald et al.
2007/0016070 A1 1/2007 Grunwald et al.
2007/0016072 A1 1/2007 Grunwald et al.
2007/0032746 A1 2/2007 Sell
2007/0038113 A1 2/2007 Oonuki et al.
2007/0049822 A1 3/2007 Bunce et al.
2007/0049846 A1 3/2007 Bown et al.
2007/0055141 A1 3/2007 Kruger et al.
2007/0055142 A1 3/2007 Webler
2007/0060992 A1 3/2007 Pappone
2007/0062544 A1 3/2007 Rauk Bergstrom et al.
2007/0066888 A1 3/2007 Maschke
2007/0073155 A1 3/2007 Park et al.
2007/0087038 A1 4/2007 Richardson et al.
2007/0093710 A1 4/2007 Maschke
2007/0100236 A1 5/2007 McMorrow et al.
2007/0100285 A1 5/2007 Griffin et al.
2007/0112282 A1 5/2007 Skujins et al.
2007/0123805 A1 5/2007 Shireman et al.
2007/0129770 A1 6/2007 Younis
2007/0135803 A1 6/2007 Belson
2007/0135886 A1 6/2007 Maschke
2007/0156205 A1 7/2007 Larson et al.
2007/0161853 A1 7/2007 Yagi et al.
2007/0161914 A1 7/2007 Zdeblick et al.
2007/0161915 A1 7/2007 Desai
2007/0167738 A1 7/2007 Timinger et al.
2007/0167762 A1 7/2007 Kim et al.
2007/0167769 A1 7/2007 Ikuma et al.
2007/0167801 A1 7/2007 Webler et al.
2007/0167997 A1 7/2007 Forsberg et al.
2007/0197891 A1 8/2007 Shachar et al.
2007/0197905 A1 8/2007 Timinger et al.
2007/0208255 A1 9/2007 Ridley et al.
2007/0219453 A1 9/2007 Kremliovsky et al.
2007/0225589 A1 9/2007 Viswanathan
2007/0225610 A1 9/2007 Mickley et al.
2007/0232882 A1 10/2007 Glossop et al.
2007/0232896 A1 10/2007 Gilboa et al.
2007/0238984 A1 10/2007 Maschke et al.
2007/0239018 A1 10/2007 Fetzer et al.
2007/0244413 A1 10/2007 Biggins
2007/0247454 A1 10/2007 Rahn et al.
2007/0249911 A1 10/2007 Simon
2007/0255270 A1 11/2007 Carney
2007/0265526 A1 11/2007 Govari et al.
2007/0280974 A1 12/2007 Son et al.
2007/0282196 A1 12/2007 Birk et al.
2007/0282197 A1 12/2007 Bill et al.
2007/0299352 A1 12/2007 Harlev et al.
2007/0299353 A1 12/2007 Harlev et al.
2008/0004652 A1 1/2008 Abboud et al.
2008/0008745 A1 1/2008 Stinchcomb et al.
2008/0009720 A1 1/2008 Schefelker et al.
2008/0015442 A1 1/2008 Watson et al.
2008/0027320 A1 1/2008 Bolorforosh et al.
2008/0033283 A1 2/2008 Dellaca et al.
2008/0033316 A1 2/2008 Kassab et al.
2008/0033350 A1 2/2008 Wilson et al.
2008/0045908 A1 2/2008 Gould et al.
2008/0051626 A1 2/2008 Sato et al.
2008/0077158 A1 3/2008 Haider et al.
2008/0081958 A1 4/2008 Denison et al.
2008/0082136 A1 4/2008 Gaudiani
2008/0097232 A1 4/2008 Rothenberg
2008/0108949 A1 5/2008 Beasley et al.
2008/0114095 A1 5/2008 Peppmoller et al.
2008/0125772 A1 5/2008 Stone et al.
2008/0139944 A1 6/2008 Weymer et al.
2008/0146939 A1 6/2008 McMorrow et al.
2008/0146940 A1 6/2008 Jenkins et al.
2008/0146942 A1 6/2008 Dala-Krishna
2008/0154100 A1 6/2008 Thalmeier et al.
2008/0166453 A1 7/2008 Steele et al.
2008/0171934 A1 7/2008 Greenan et al.
2008/0183075 A1 7/2008 Govari et al.
2008/0188830 A1 8/2008 Rosenblatt et al.
2008/0190438 A1 8/2008 Harlev et al.
2008/0195169 A1 8/2008 Pinter et al.
2008/0200754 A1 8/2008 Buchalter
2008/0228082 A1 9/2008 Scheirer et al.
2008/0236598 A1* 10/2008 Gobel 128/849
2008/0255404 A1 10/2008 Nogawa et al.
2008/0255475 A1 10/2008 Kondrosky et al.
2008/0269581 A1 10/2008 Wood et al.
2008/0269611 A1 10/2008 Pedrizzetti et al.
2008/0275465 A1 11/2008 Paul et al.
2008/0275765 A1 11/2008 Kuchar
2008/0288038 A1 11/2008 Paul et al.
2008/0294041 A1 11/2008 Kassab
2008/0319350 A1 12/2008 Wallace et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2009/0005674 A1 1/2009 Saadat et al.
2009/0005675 A1 1/2009 Grunwald et al.
2009/0018497 A1 1/2009 Birchard et al.
2009/0024018 A1 1/2009 Boyden et al.
2009/0030380 A1 1/2009 Binmoeller
2009/0043205 A1 2/2009 Pelissier et al.
2009/0062684 A1 3/2009 Gregersen et al.
2009/0082661 A1 3/2009 Saladin et al.
2009/0084382 A1 4/2009 Jalde et al.
2009/0101577 A1 4/2009 Fulkerson et al.
2009/0118612 A1 5/2009 Grunwald et al.
2009/0118637 A1 5/2009 Kassab et al.
2009/0118706 A1 5/2009 Schweikert et al.
2009/0124901 A1 5/2009 Fink et al.
2009/0143736 A1 6/2009 Mittermeyer et al.
2009/0156926 A1 6/2009 Messerly et al.
2009/0163810 A1 6/2009 Kanade et al.
2009/0171217 A1 7/2009 Kim et al.
2009/0177083 A1 7/2009 Matsumura
2009/0177090 A1 7/2009 Grunwald et al.
2009/0203989 A1 8/2009 Burnside et al.
2009/0204113 A1 8/2009 MacAdam et al.
2009/0209872 A1 8/2009 Pop
2009/0209950 A1 8/2009 Starksen
2009/0221908 A1 9/2009 Glossop
2009/0227952 A1 9/2009 Blakstvedt et al.
2009/0234328 A1 9/2009 Cox et al.
2009/0253976 A1 10/2009 Harlev et al.
2009/0258171 A1 10/2009 Uang
2009/0259124 A1 10/2009 Rothenberg
2009/0262982 A1 10/2009 Markowitz et al.
2009/0270729 A1 10/2009 Corbucci et al.
2009/0270746 A1 10/2009 Min
2009/0275828 A1 11/2009 Shachar et al.
2009/0297441 A1 12/2009 Canham et al.
2010/0004543 A1 1/2010 Ahlund et al.
2010/0004547 A1 1/2010 Scholz et al.
2010/0010355 A1 1/2010 Kassab
2010/0010444 A1 1/2010 Bettuchi
2010/0010612 A1 1/2010 Gelbart et al.
2010/0016726 A1 1/2010 Meier
2010/0036227 A1 2/2010 Cox et al.
2010/0036284 A1 2/2010 Laynes et al.
2010/0041973 A1 2/2010 Vu et al.
2010/0041984 A1 2/2010 Shapland et al.
2010/0049062 A1 2/2010 Ziv
2010/0055153 A1 3/2010 Majmudar
2010/0055184 A1 3/2010 Zeitels et al.
2010/0057157 A1 3/2010 Govari et al.
2010/0060472 A1 3/2010 Kimura et al.
2010/0063401 A1 3/2010 Nishina et al.
2010/0076305 A1 3/2010 Maier-Hein et al.
2010/0076328 A1 3/2010 Matsumura et al.
2010/0081934 A1 4/2010 Soltani et al.
2010/0083719 A1 4/2010 Peppmoller et al.
2010/0094116 A1 4/2010 Silverstein
2010/0106011 A1 4/2010 Byrd et al.
2010/0114573 A1 5/2010 Huang et al.
2010/0117659 A1 5/2010 Osadchy et al.
2010/0143119 A1 6/2010 Kooijman et al.
2010/0152596 A1 6/2010 Griffiths et al.
2010/0168557 A1 7/2010 Deno et al.
2010/0185097 A1 7/2010 Hall
2010/0198048 A1 8/2010 Togawa
2010/0198346 A1 8/2010 Keogh et al.
2010/0204569 A1 8/2010 Burnside et al.
2010/0204614 A1 8/2010 Lindquist et al.
2010/0210938 A1 8/2010 Verard et al.
2010/0210950 A1 8/2010 Dunbar et al.
2010/0217116 A1 8/2010 Eck et al.
2010/0222664 A1 9/2010 Lemon et al.
2010/0222786 A1 9/2010 Kassab
2010/0234724 A1 9/2010 Jacobsen et al.
2010/0234733 A1 9/2010 Wahlheim
2010/0249598 A1 9/2010 Smith et al.
2010/0258033 A1 10/2010 Yang et al.
2010/0268059 A1 10/2010 Ryu et al.
2010/0273895 A1 10/2010 Stinchcomb et al.
2010/0291521 A1 11/2010 Simon
2010/0298702 A1 11/2010 Rogers et al.
2010/0298704 A1 11/2010 Pelissier et al.
2010/0298705 A1 11/2010 Pelissier et al.
2010/0298712 A1 11/2010 Pelissier et al.
2010/0312086 A9 12/2010 Beatty et al.
2010/0317981 A1 12/2010 Grunwald
2010/0318026 A1 12/2010 Grunwald
2010/0331712 A1 12/2010 Rothenberg
2011/0015527 A1 1/2011 Heasty et al.
2011/0015533 A1 1/2011 Cox et al.
2011/0034823 A1 2/2011 Gelbart et al.
2011/0034940 A1 2/2011 Payner
2011/0040212 A1 2/2011 Dietz et al.
2011/0052694 A1 3/2011 Stinchcomb et al.
2011/0087105 A1 4/2011 Ridley et al.
2011/0087106 A1 4/2011 Ridley et al.
2011/0087107 A1 4/2011 Lindekugel et al.
2011/0112396 A1 5/2011 Shachar et al.
2011/0136242 A1 6/2011 Marx et al.
2011/0137156 A1 6/2011 Razzaque et al.
2011/0196235 A1 8/2011 Dunbar et al.
2011/0196248 A1 8/2011 Grunwald
2011/0196255 A1 8/2011 Kassab
2011/0237935 A1 9/2011 Kalpin et al.
2011/0245659 A1 10/2011 Ma et al.
2011/0282187 A1 11/2011 Harlev et al.
2011/0282188 A1 11/2011 Burnside et al.
2011/0282285 A1 11/2011 Blanchard et al.
2011/0295108 A1 12/2011 Cox et al.
2011/0306867 A1 12/2011 Gopinathan et al.
2011/0313293 A1 12/2011 Lindekugel et al.
2012/0004564 A1 1/2012 Dobak, III
2012/0035460 A1 2/2012 Stangenes et al.
2012/0046562 A1 2/2012 Powers et al.
2012/0059249 A1 3/2012 Verard et al.
2012/0059270 A1 3/2012 Grunwald
2012/0071751 A1 3/2012 Sra et al.
2012/0071759 A1 3/2012 Hagy et al.
2012/0071782 A1 3/2012 Patil et al.
2012/0078342 A1 3/2012 Vollkron et al.
2012/0095319 A1 4/2012 Kondrosky et al.
2012/0108950 A1 5/2012 He et al.
2012/0143029 A1 6/2012 Silverstein et al.
2012/0143078 A1 6/2012 Kassab et al.
2012/0172727 A1 7/2012 Hastings et al.
2012/0283582 A1 11/2012 Mahapatra et al.
2012/0296200 A1 11/2012 Shachar et al.
2012/0310052 A1 12/2012 Mahapatra et al.
2012/0310066 A1 12/2012 Shachar et al.
2012/0316440 A1 12/2012 Munrow et al.
2013/0006102 A1 1/2013 Wilkes et al.
2013/0018248 A1 1/2013 Hurezan
2013/0035590 A1 2/2013 Ma et al.
2013/0041269 A1 2/2013 Stahmann et al.
2013/0060116 A1 3/2013 Messerly et al.
2013/0085416 A1 4/2013 Mest
2013/0102890 A1 4/2013 Dib
2013/0123597 A1 5/2013 Rothenberg
2013/0169272 A1 7/2013 Eichler et al.
2013/0217999 A1* 8/2013 Burnside A61B 1/00158 600/409
2013/0245434 A1 9/2013 Messerly et al.
2013/0296691 A1 11/2013 Ashe
2013/0303896 A1 11/2013 Kalpin et al.
2013/0317338 A1 11/2013 Silverstein
2013/0324841 A1 12/2013 Kamen et al.
2013/0338503 A1 12/2013 Cohen et al.
2013/0338517 A1 12/2013 Rothenberg
2013/0345555 A1 12/2013 Kanade et al.
2014/0031674 A1 1/2014 Newman et al.
2014/0046261 A1 2/2014 Newman et al.
2014/0094694 A1 4/2014 Moctezuma de la Barrera
2014/0094768 A1 4/2014 Stangenes et al.
2014/0107475 A1 4/2014 Cox et al.
2014/0163356 A2 6/2014 Burnside et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2014/0180074	A1	6/2014	Green et al.	
2014/0187990	A1	7/2014	Banet et al.	
2014/0188133	A1	7/2014	Misener	
2014/0228689	A1	8/2014	Ishikawa et al.	
2014/0243659	A1	8/2014	Rothenberg	
2014/0249505	A1	9/2014	Bukhman	
2014/0257080	A1	9/2014	Dunbar et al.	
2014/0275957	A1	9/2014	Lupotti	
2014/0275990	A1	9/2014	Hagy et al.	
2014/0303492	A1	10/2014	Burnside et al.	
2014/0309624	A1	10/2014	Bown et al.	
2014/0343398	A1*	11/2014	He	A61B 5/068 600/409
2015/0005621	A1	1/2015	Liu	
2015/0018701	A1*	1/2015	Cox	A61B 5/06 600/521
2015/0025402	A1	1/2015	Rothenberg	
2015/0051489	A1	2/2015	Caluser et al.	
2015/0080716	A1	3/2015	Powers et al.	
2015/0216446	A1*	8/2015	Bukhman	A61B 5/062 600/409
2015/0297114	A1*	10/2015	Cox	A61B 5/042 600/374
2016/0374589	A1	12/2016	Misener et al.	
2017/0000367	A1	1/2017	Grunwald	
2017/0020561	A1	1/2017	Cox et al.	
2017/0079548	A1	3/2017	Silverstein et al.	
2017/0079552	A1	3/2017	Grunwald	
2017/0079615	A1	3/2017	Burnside et al.	
2017/0079681	A1	3/2017	Burnside et al.	

FOREIGN PATENT DOCUMENTS

AU	20009592		9/2000
AU	20015250		6/2001
AU	768362	B2	12/2003
AU	2001229024	B2	9/2005
AU	2001283703	B2	5/2006
AU	2006202149		6/2006
AU	2006904933		9/2006
AU	2006283022	B2	2/2012
CA	2420676		2/2002
CA	2619909	C	1/2014
CN	2031655	U	2/1989
CN	1672649	A	9/2005
CN	1913833	A	2/2007
CN	102209490	A	10/2011
CN	102802514	A	11/2012
CN	102821679	A	12/2012
CN	103037761	A	4/2013
CN	103037762	A	4/2013
CN	103118591	A	5/2013
CN	103189009	A	7/2013
DE	4319033	C1	6/1994
EP	0359697		3/1990
EP	0362821		4/1990
EP	0399536	A1	11/1990
EP	0823261	A2	2/1998
EP	0928976	A2	7/1999
EP	1025805	A1	8/2000
EP	1311226	A1	5/2003
EP	1504713	A1	2/2005
EP	1932477	A1	6/2008
EP	2313143	A1	4/2011
EP	2337491	A1	6/2011
EP	2440122	A1	4/2012
EP	2464407	A2	6/2012
EP	2482719	A1	8/2012
EP	2575610	A1	4/2013
EP	2575611	A1	4/2013
EP	2603145	A2	6/2013
EP	2605699	A2	6/2013
EP	2618727	A1	7/2013
EP	2632360	A1	9/2013
EP	2219526	B1	3/2014
EP	2712547	A1	4/2014
FR	2545349		11/1984
IN	9721/DELNP/2011		1/2013
JP	01097440		4/1989
JP	03173542	A	7/1991
JP	4090741		8/1992
JP	9-503054		3/1997
JP	09-094298	A	4/1997
JP	10043310		2/1998
JP	10290839	A	11/1998
JP	11128237	A	5/1999
JP	2001161683		6/2001
JP	2001-514533	A	9/2001
JP	2001-524339	A	12/2001
JP	2001340334		12/2001
JP	2002-224069	A	8/2002
JP	2002-529133	A	9/2002
JP	2002-541947	A	12/2002
JP	2003-010138	A	1/2003
JP	2003501127	A	1/2003
JP	2003061752	A	3/2003
JP	2003299654		10/2003
JP	2003334191		11/2003
JP	2002520893		2/2004
JP	2004505748	T	2/2004
JP	2004515298	A	5/2004
JP	2006508744	A	3/2006
JP	2006-338526	A	12/2006
JP	2007-000226	A	1/2007
JP	2007-068989	A	3/2007
JP	2007-313122	A	12/2007
JP	2009/271123	A	11/2009
JP	5010604		6/2012
JP	2012-529929		11/2012
JP	2013-518676	A	5/2013
JP	2013-526959	A	6/2013
JP	2013-526961	A	6/2013
WO	8002376	A1	11/1980
WO	9112836	A1	9/1991
WO	9203090		3/1992
WO	9403159	A1	2/1994
WO	9404938		3/1994
WO	9605768	A1	2/1996
WO	9607352	A1	3/1996
WO	9641119		12/1996
WO	9729683	A1	8/1997
WO	9743989	A1	11/1997
WO	9825159	A1	6/1998
WO	98/29032	A1	7/1998
WO	9835611	A1	8/1998
WO	9916495	A1	4/1999
WO	9927837	A2	6/1999
WO	9949407	A1	9/1999
WO	0019906		4/2000
WO	0027281	A1	5/2000
WO	0040155		7/2000
WO	0063658	A2	10/2000
WO	0074775	A1	12/2000
WO	0113792	A1	3/2001
WO	0139683	A1	6/2001
WO	0176479	A1	10/2001
WO	0215973	A1	2/2002
WO	0219905	A1	3/2002
WO	0225277	A1	3/2002
WO	02085442	A1	10/2002
WO	2003061752		7/2003
WO	2003077759	A1	9/2003
WO	03/088833	A1	10/2003
WO	03091495	A1	11/2003
WO	2004002303	A1	1/2004
WO	2004049970	A2	6/2004
WO	2005033524	A1	4/2005
WO	2005033574	A1	4/2005
WO	2005117690	A1	12/2005
WO	2005117733	A2	12/2005
WO	2006074509	A1	7/2006
WO	2006074510	A1	7/2006
WO	2006078677	A2	7/2006

(56) **References Cited**

FOREIGN PATENT DOCUMENTS

WO	2006103661	A2	10/2006
WO	2006111056	A1	10/2006
WO	2007002541	A2	1/2007
WO	2007005976	A1	1/2007
WO	2007014447	A1	2/2007
WO	2007034196	A2	3/2007
WO	2007067324	A1	6/2007
WO	2007069168	A2	6/2007
WO	2007109123	A2	9/2007
WO	2007126536	A2	11/2007
WO	2007144894	A1	12/2007
WO	2008005480	A1	1/2008
WO	2008024596	A2	2/2008
WO	2008028253		3/2008
WO	2008083111		7/2008
WO	2008097767	A2	8/2008
WO	2008118992	A1	10/2008
WO	2008126074	A2	10/2008
WO	2008129326	A1	10/2008
WO	2008131017	A2	10/2008
WO	2008136008	A2	11/2008
WO	2009000439	A1	12/2008
WO	2009002514	A2	12/2008
WO	2009003138	A1	12/2008
WO	2009009064	A1	1/2009
WO	2009057774	A1	5/2009
WO	2009063166	A1	5/2009
WO	2009067654	A1	5/2009
WO	2009070616	A2	6/2009
WO	2009100158	A1	8/2009
WO	2009123819	A2	10/2009
WO	2009126340	A1	10/2009
WO	2009129475	A1	10/2009
WO	2009129477	A1	10/2009
WO	2009134605	A2	11/2009
WO	2009137262	A2	11/2009
WO	2010002313	A1	1/2010
WO	2010018500	A1	2/2010
WO	2010022370	A1	2/2010
WO	2010027349	A1	3/2010
WO	2010027471	A2	3/2010
WO	2010029906	A1	3/2010
WO	2010030820	A1	3/2010
WO	2010132857	A1	11/2010
WO	2010132985	A1	11/2010
WO	2010143196	A1	12/2010
WO	2010144922	A1	12/2010
WO	2011019760	A2	2/2011
WO	2011041450	A1	4/2011
WO	2011044421	A1	4/2011
WO	2011057289	A2	5/2011
WO	2011064209	A1	6/2011
WO	2011084593	A2	7/2011
WO	2011097312	A1	8/2011
WO	2011128052	A2	10/2011
WO	2011150358	A1	12/2011
WO	2011150376	A1	12/2011
WO	2012021542	A2	2/2012
WO	2012024577	A2	2/2012
WO	2012039866	A1	3/2012
WO	2012040487	A1	3/2012
WO	2012058461	A1	5/2012
WO	2012083245	A1	6/2012
WO	2012088535	A1	6/2012
WO	2012110955	A1	8/2012
WO	2012173697	A1	12/2012
WO	2013006713	A2	1/2013
WO	2013006817	A1	1/2013
WO	2013034175	A1	3/2013
WO	2014052894	A2	4/2014
WO	2014062728	A1	4/2014
WO	2014138652	A1	9/2014
WO	2014138918	A1	9/2014
WO	2015/120256	A2	8/2015
WO	2016/210325	A1	12/2016

OTHER PUBLICATIONS

Acuson—The Value of Vision, AcuNav Diagnostic Ultrasound Catheter, 2000.

Advertising flyer for GAVECELT—The Italian Group for Long Term Venous Access Devices, for program on International Meeting on PICC's, Midline Catheters and Long Term Venous Access Devices in Catholic University, Rome, Italy on Dec. 3, 4, 5, 2008.

Alexander, GD et al, The Role of Nitrous Oxide in Postoperative Nausea and Vomiting, Collection of Abstracts Presented at the International Anesthesia Research Society by various speakers, 58th Congress, Mar. 12-14, 1984, Anesthesia and Analgesia, pp. 175-284, vol. 63, 1984.

Allan, P.L. et al, Role of Ultrsound in the Assessment of Chronic Venous Insufficiency, Ultrasound Quarterly, vol. 17, No. 1, pp. 3-10, 2001.

Andropoulos, et al. "A Controlled Study of the Transesophageal Echocardiography to Guide Central Venous Catheter Placement in Congetital Heart Surgery Patients." The International Anesthesia Research Society, vol. 89, pp. 65-70, 1999.

Anonymous author, Correct Catheter Placement with a low-impact, reliable and economical method, <http://www.cvc-partner.com/index.cfm?103A955CC6844BF58ACFE3C9C1471959>, last accessed Dec. 22, 2011.

Arai, J et al, Detection of Peripherally Inserted Central Catheter Occlusion by in-line Pressure Monitoring, Paediatr Anaesth, pp. 621-624, vol. 12 No. 7, Sep. 2002.

Arrow International, Inc., The Arrow-Johans RAECG Adapter-Making Proper Central Venous Catheter Placement More Reliable (Modle No. EG-04900), Technical Report 1987, USA.

Aslamy, et al. "MRI of Central Venous Anatomy: Implications for Central Venous Catheter Insertion." American College of Chest Physicians, Jun. 8, 2009.

AU 2006283022 filed Aug. 24, 2006 Office Action dated Dec. 22, 2010.

AURORA® System Technical Specifications 2004.

B. Braun Website, "The Optimal Position of the Central Venous Catheter." http://www.cvcpartner.com/index.cfm18F1BDEA1310466194960A39F4E90968 (2009).

B. Braun, Certofix Central Venous Catheter for Placement Using the Seldinger Technique with Simultaneous ECG Lead Option, Feb. 2010.

Bailey, SH et al, Is Immediate Chest Radiograph Necessary after Central Venous Catheter Placement in a Surgical Intensive Care Unit?, Am J Surg, pp. 517-522, vol. 180 No. 6, Dec. 2000.

Bankier, Alexander A., Azygos Arch Cannulation by Central Venous Catheters: Radiographic Detection of Malposition and Subsequent Complications, Journal of Thoracic Imaging 12:64-69 (1997).

Barber, JM et al, A Nurse led Peripherally Inserted Central Catheter Line Insertion Service is Effective with Radiological Support, Clin Radiol, pp. 352-354, vol. 57 No. 5, May 2002.

Bard Access Systems, Sherlock Tip Location System, 5 pages, 2006.

Bard Access Systems, Site Rite Vascular Acess Ultrasound System, 4 pages, 2005.

Benchimol, Alberto at al, Right Atrium and Superior Vena Cava Flow Velocity in Man Measured with the Doppler-Catheter Flowmeter-Telemetry System, The Amer Journal of Medicine, pp. 303-309, vol. 48, Mar. 1970.

BioAdvance Lumen Vu, Greenhouse Fund Feb. 2004 Recipient, www.bioadvance.com <http://www.bioadvance.com>, 2005.

Borgobello, Bridget, App allows users to view electrocardiograms on smartphones dated Oct. 15, 2010; printed from http://www.gizmag.com/app-to-view-electrocardiograms-on-smartphones/16664/ on Feb. 4, 2011.

Buehrle, Douglas, PICC Placement in Humans using Electromagnetic Detection, <http://www.corpakmedsystems.com/supplement_material/supplementpages/navigator/navarticle.html>, 2008.

C.R. Bard, CathTrack™ Catheter Location System at www.bardaccess.com <http://www.bardaccess.com>, last accessed Apr. 28, 2011.

C.R. Bard, Inc., Bard Electrophysiology Product Catalogue, Bard Catheters, pp. 74-75 (2002), USA.

(56) **References Cited**

OTHER PUBLICATIONS

Cadman, A et al, To Clot or Not to Clot? That is the question in Central Venous Catheters, Clinical Radiology, pp. 349-355, vol. 59 No. 4, Apr. 2004.
Calvert, N et al, The Effectiveness and Cost-effectiveness of Ultrasound Locating Devices for Central Venous Access: A Systematic Review and Economic Evaluation, Health Technology Assessment, vol. 7, No. 12, 2003.
Cardella, John F. et al., Interventinal Radiologic Placement of Peripherally Inserted Central Catheters, Journal of Vascular and Interventional Radiology 1993; 4:653-660.
Carlon, R et al, Secondary Migration of a Central Venous Catheter—A Case Report, Minerva Anestesiol, pp. 927-931, vol. 69 No. 12, Dec. 2003.
Caruso, LJ et al, A Better Landmark for Positioning a Central Venous Catheter, J Clinical Monitoring and Computing, pp. 331-334, vol. 17 No. 6, Aug. 2002.
Cavatorta, et al., "Central Venous Catheter Placement in Hemodialysis: Evaluation of Electrocardiography Using a Guidewire." The Journal of Vascular Access, vol. 2, pp. 45-50, 2001.
Chalkiadis, GA et al, Depth of Central Venous Catheter Insertion in Adults: An Audit and Assessment of a Technique to Improve Tip Position, Anaesth Intensive Care, pp. 61-66, vol. 26 No. 1, Feb. 1998.
Chamsi-Pasha, Hassan et al, Cardiac Complications of Total Parenteral Nutrition: The Role of Two-Dimensional Echocardiography in Diagnosis, Annals of the Royal College of Surgeons of England, pp. 120-123, vol. 71, 1989.
Chang, Thomas C. et al., Are Routine Ch Ladiographs Necessary After Image-Guided Placement of Internal Jugular Central Venous Access Devices?, AJR Feb. 1998;170:335-337.
Chaturvedi et al., "Catheter Malplacement During Central Venous Cannulation Through Arm Veins in Pediatric Patients." Journal of Neurosurgical Anesthesiology, vol. 15, No. 3 pp. 170-175, Jan. 2003.
Chen, Zhongping et al, Optical Doppler Tomography: Imaging in vivo Blood Flow Dynamics Following Pharmacological Intervention and Photodynamic Therapy, 7 pages, vol. 67, Photochemistry and Photobiology, 1998.
Cheng, KI et al, A Novel Approach of Intravenous Electrocardiograph Technique in Correct Position the Long-Term Central Venous Catheter, Kaohsiung J Med Sci, pp. 241-247, vol. 16 No. 5, May 2000 (Abstract only).
Cheung, P., et al., The Effect of a Disposable Probe Cover on Pulse Oximetry, Anaesth Intensive Care 2002; 30:211-214.
Chu, et al., "Accurate Central Venous Port-A Catheter Placement: Intravenous Electrocardiography and Surface Landmark Techniques Compared by Using Transesophageal Echocardiography." The International Anesthesia Research Society, vol. 98, pp. 910-914, 2004.
Claasz, Antonia et al, A Study of the Relationship of the Superior Vena Cava to the Bony Landmarks of the Sternum in the Supine Adult: Implications for Magnetic Guidance Systems, Journal, vol. 12 No. 3, JAVA, Jul. 24, 2007.
Clifford, et al. "Assessment of Hepatic Motion Secondary to Respiration for Computer Assisted Interventions." Computer Aided Surgery, vol. 7, pp. 291-299, 2002.
CN 200880012117.4 filed Apr. 16, 2008 First Office Action dated Dec. 23, 2011.
Colley, Peter S et al, ECG-Guided Placement of Sorenson CVP Catheters via Arm Veins, Anesthesia and Analgesia, pp. 953-956, vol. 63, 1984.
Collier, PE et al, Cardiac Tamponade from Central Venous Catheters, Am J Surg, pp. 212-214, vol. 176 No. 2, Aug. 1998.
ComboWire® Pressure/Flow Guide Wire Ref 9500 Series, Instructions for Use, Apr. 2011.
Corsten, et al., "Central Placement Catheter Placement Using the ECG-Guided Cavafix-Certodyn SD Catheter." Journal of Clinical Anesthesiology, vol. 6, Nov./Dec. 1994.
Cucchiara, Roy et al, Time Required and Success Rate of Percantaneous Right Atrial Catherization: Description of a Technique, Canad. Anaesth. Soc. J., pp. 572-573, vol. 27, No. 6, Nov. 1980.
Cullinane, DC et al, The Futility of Chest Roentgenograms Following Routine Central Venous Line Changes, Am J Surg, pp. 283-285, vol. 176 No. 3, Sep. 1998.
Curet, Myriam J. et al., University and Practice-based Physicians' Input on the Content of a Surgical Curriculum, The American Journal of Surgery® vol. 178 Jul. 1999, 78-84.
David, et al., "Is ECG-Guidance a Helpful Method to Correctly Position a Central Venous Catheter During Prehospital Emergency Care?" ACTA Anaesthesiologica Scandinavica, vol. 49, pp. 1010-1014, 2005.
Micronix Pty Ltd "CathRite" Guiding Styled Core Manufacturing, Jun. 15, 2006.
Murthy, Vrudhula et al, Analysis of Power Spectral Densities of Electrocardiograms, Mathematical Biosciences, pp. 41-51, vol. 12 No. 1-2, Oct. 1971.
Nadroo, AM et al, Changes in Upper Extremity Position Cause Migration of Peripherally Inserted Central Catheters in Neonates, Pediatrics, pp. 131-136, vol. 110, Jul. 2002.
Nakatani, K et al, Accurate Placement of Central Venous Catheters—ECG-guided method vs Patient Height Method, Masui, pp. 34-38, vol. 51 No. 1, Jan. 2002.
Nazarian, GK et al, Changes in Tunneled Catheter Tip Position when a patient is Upright, J Vasc Interv Radiol, pp. 437-441, vol. 8 No. 3, May-Jun. 1997.
Neurometer® CPT, Clinical Applications. Neurotron , Inc. website: www.neurotron.com/CLINAPS.html, last accessed Oct. 23, 2006.
Neurometer® CPT, Frequently Asked Questions. Neurotron , Inc. website: www.neurotron.com/CPTFAQ/html, last accessed Oct. 23, 2006.
Neurometer® CPT, Products Page. Neurotron , Inc. website: www.neurotron.com/products.html, last accessed Oct. 23, 2006.
Neurometer® Electrodiagnostic Neuroselective Sensory Nerve Evaluation: Charts, Tables, Documents & Downloads. Neurotron , Inc. website: www.neurotron.com/downloads.html, last accessed Oct. 23, 2006.
Odd, De et al, Does Radio-opaque Contrast Improve Radiographic localisation of Percutaneous Central Venous Lines?, Arch Dis Child Fetal Neonatal Ed, pp. 41-43, vol. 89 No. 1, Jan. 2004.
Palesty, JA et al, Routine Chest Radiographs Following Central Venous Recatherization over a Wire are not Justified, Am J Surg, pp. 618-621, vol. 176 No. 6, Dec. 1998.
Paliotti, Roberta P. et al, Intravascular Doppler Technique for Monitoring Renal Venous Blood Flow in Man, J Nephrol, pp. 57-62, 2003.
Parker, K.H. et al, Cardiovascular Fluid Dynamics, Department of Bioengineering, National Heart and Lung Institute, Imperial College of Science, Technology and Medicine, Cardiovascular Haemodynamics, pp. 1-28, Sep. 26, 2005.
Pawlik, et al., "Central Venous Catheter Placement: Comparison of the Intravascular Guidewire and the Fluid Column Electrocardiograms." European Journal of Anaesthesiology, vol. 41, pp. 594-599, 2004.
PCT/US2006/033079 filed Aug. 24, 2006 International Preliminary Report on Patentability dated Feb. 26, 2008.
PCT/US2006/033079 filed Aug. 24, 2006 Search Report dated Dec. 19, 2006.
PCT/US2006/033079 filed Aug. 24, 2006 Written Opinion dated Dec. 19, 2006.
PCT/US2008/060502 filed Apr. 16, 2008 International Search Report and Written Opinion dated Oct. 16, 2008.
PCT/US2008/084751 filed Nov. 25, 2008 International Preliminary Report on Patentability dated Jun. 1, 2010.
PCT/US2008/084751 filed Nov. 25, 2008 Search Report dated May 20, 2009.
PCT/US2008/084751 filed Nov. 25, 2008 Written Opinion dated May 20, 2009.
PCT/US2009/033116 filed Feb. 4, 2009 International Preliminary Report on Patentability dated Aug. 10, 2010.

(56) **References Cited**

OTHER PUBLICATIONS

PCT/US2009/033116 filed Feb. 4, 2009 Search Report dated Mar. 13, 2009.
PCT/US2009/033116 filed Feb. 4, 2009 Written Opinion dated Mar. 13, 2009.
PCT/US2009/041051 filed Apr. 17, 2009 Search Report dated Jul. 28, 2009.
PCT/US2009/041051 filed Apr. 17, 2009 Written Opinion dated Jul. 28, 2009.
PCT/US2009/054687 filed Aug. 21, 2009 International Preliminary Report on Patentability dated Feb. 22, 2011.
PCT/US2009/054687 filed Aug. 21, 2009 Search Report dated Oct. 6, 2009.
PCT/US2009/054687 filed Aug. 21, 2009 Written Opinion dated Oct. 6, 2009.
PCT/US2009/056567 filed Sep. 10, 2009 International Preliminary Report on Patentability dated Mar. 15, 2011.
PCT/US2009/056567 filed Sep. 10, 2009 Search Report dated Nov. 6, 2009.
PCT/US2009/056567 filed Sep. 10, 2009 Written Opinion dated Nov. 6, 2009.
PCT/US2010/038555 filed Jun. 14, 2010 Search Report dated Oct. 5, 2010.
PCT/US2010/038555 filed Jun. 14, 2010 Written Opinion dated Oct. 5, 2010.
PCT/US2010/045084 filed Aug. 10, 2010 International Preliminary Report on Patentability dated Feb. 23, 2012.
PCT/US2010/045084 filed Aug. 10, 2010 Search Report dated Apr. 14, 2011.
PCT/US2010/045084 filed Aug. 10, 2010 Written Opinion dated Apr. 14, 2011.
PCT/US2010/050773 filed Sep. 29, 2010 Search Report dated Jan. 24, 2011.
PCT/US2010/050773 filed Sep. 29, 2010 Written Opinion dated Jan. 24, 2011.
PCT/US2010/051917 filed Oct. 8, 2010 Search Report dated Nov. 29, 2010.
PCT/US2010/051917 filed Oct. 8, 2010 Written Opinion dated Nov. 29, 2010.
PCT/US2011/023497 filed Feb. 2, 2011 Search Report dated Jun. 6, 2011.
PCT/US2011/023497 filed Feb. 2, 2011 Written Opinion dated Jun. 6, 2011.
PCT/US2011/038415 filed May 27, 2011 International Search Report dated Sep. 28, 2011.
PCT/US2011/038415 filed May 27, 2011 Written Opinion dated Sep. 28, 2011.
PCT/US2011/047127 filed Aug. 9, 2011 International Search Report dated Feb. 29, 2012.
PCT/US2011/047127 filed Aug. 9, 2011 Written Opinion dated Feb. 29, 2012.
PCT/US2011/048403 filed Aug. 19, 2011 International Search Report dated Dec. 15, 2011.
PCT/US2011/048403 filed Aug. 19, 2011 Written Opinion dated Dec. 15, 2011.
PCT/US2011/052793 filed Sep. 22, 2011 International Search Report dated Jan. 6, 2012.
PCT/US2011/052793 filed Sep. 22, 2011 Written Opinion dated Jan. 6, 2012.
PCT/US2011/067268 filed Dec. 23, 2011 International Search Report and Written Opinion dated Apr. 27, 2012.
Pennington, C.R., Right Atrial Thrombus: a Complication of Total Parenteral Nutrition, British Medical Journal, pp. 446-447, vol. 295, Aug. 15, 1987.
Petersen, J et al, Silicone Venous Access Devices Positioned with their Tip High in the Superior Vena Cava are More Likely to Malfunction, Am J Surg, pp. 38-41, vol. 178 No. 1, Jul. 1999.
Pittiruti, et al, Intracavitary EKG Monitoring: A reliable method for controlling tip position during and after PICC Insertion presentation in Catholic University, Rome, Italy in 2008.
Pittiruti, et al. "The EKG Method for Positioning the Tip of PICCs: Results from Two Preliminary Studies." JAVA, vol. 13, No. 4, pp. 179-185, 2008.
Polos, PG et al, Tips for Monitoring the Position of a Central Venous Catheter—How Placement can go awry—even when the anatomy is normal, J Crit Illn, pp. 660-674, vol. 8 No. 6, Jun. 1993 (Abstract only).
Popp, M. B. et al., Accuracy of implanted port placement with the use of the electromagnetic CathTrack® catheter locator system, The Journal of Vascular Access 2005; 6: 9-12.
Randolph AG et al, Ultrasound guidance for placement of central venous catheters: a meta-analysis of the literature, Critcal Care Medicine, pp. 2053-2058, vol. 24, Dec. 1996.
Reece, A et al, Posititioning Long Lines: Contrast Versus Plain Radiography, Arch Dis Child Fetal Neonatal Ed, pp. 129-130, vol. 84 No. 2, Mar. 2001.
Reynolds, N et al, Assessment of Distal Tip Position of Long Term Central Venous Feeding Catheters using Transesophageal Echocardiology, JPEN J Parenter Enteral Nutr, pp. 39-41, vol. 25 No. 1, Jan.-Feb. 2001.
Ruschulte, Heiner et al, Prevention of Central Venous Catheter related infections with chlorhex idine gluconate impregnated wound dressings: A randomized controlled trial, presented as an abstract at the Annual meeting of the European Society of Anaesthesiologists (ESA) in Madrid, Spain in Jun. 2006, 12 pages, Annals of Hematology, Jul. 14, 2008.
Rutherford, J. S. et al., Depth of Central Venous Catheterization: An Audit of Practice in a Cardiac Surgical Unit, Anaesth Intens Care 1994; 22: 267-271.
Sacolick, et al. "Electromagnetically Tracked Placement of a Peripherally Inserted Central Catheter." SPIE Medical Imaging, 2004 Proceedings.
Salem, et al. "A New Peripherally Implanted Subcutaneous Permanent Central Venous Access Device for Patients Requiring Chemotherapy." Journal of Clinical Oncology, vol. 11, No. 11, pp. 2181-2185, Nov. 1993.
Savary, D et al, Intra-atrial Monitoring to Add Insertion of a Central Venous Line in Pre-Hospital Emergency Care Journal Europeen des Urgences, pp. 75-78, vol. 17 No. 2, 2004.
Schafer et al. "Incorrect placement of a vena cava catheter and its prevention by intra-atrial ECG." Anaesthesist. Jan. 1988;37(1):49-51.
Schummer, et al. "Central Venous Catheters—The inability of 'intra-atrial ECG' to prove adequate positioning." British Journal of Anaesthesia, vol. 93, No. 2, pp. 193-198, 2004.
Schummer, W et al, ECG-guided Central Venous Catheter Positioning: Does it detect the Pericardial Reflection rather than the Right Atrium?, Eur J Anaesthesiol, pp. 600-605, vol. 21 No. 8, Aug. 2004 (Abstract only).
Schummer, W et al, Intra-Atrial ECG is not a Reliable Method for Positioning Left Internal Jugular Vein Catheters, Br J Anaesth, pp. 481-486, vol. 91 No. 4, Oct. 2003.
Schummer, W, Central Venous Catheter—the Inability of "Intra-Atrial ECG" to prove Adequate Positioning, Br J Anaesth, pp. 193-198, vol. 93 No. 2, Aug. 2004.
Schuster, M. et al., The carina as a landmark in central venous catheter placement, British Journal of Anaesthesia 85 (2): 192-4 (2000).
Siela, Debra, Using Chest Radiography in the Intensive Care Unit, Crit Care Nurse Aug. 1, 2002 vol. 22 No. 4, pp. 18-27.
Simon, et al., "Central Venous Catheter Placement in Children: Evaluation of Electrocardiography Using J-Wire." Paediatric Anaesthesia vol. 9, pp. 501-504, 1999.
Smith, Brigham, et al., Intravenous electrocardiographic guidance for placement of peripherally inserted central catheters, Journal of Electrocardiology 43 (2010) 274-278.
Stark, DD et al, Radiographic Assessment of Venous Catheter Position in Children: Value of the Lateral View, Pediatric Radiology, pp. 76-80, vol. 14 No. 2, 1984.
Starkhammar et al. "Cath-Finder Catheter Tracking System: A New Device for Positioning of Central Venous Catheters. Early Experience from Implantation of Brachial portal Systems." Acta Anaesthesiol Scandinavia, vol. 34, No. 4 pp. 296-300, May 1990.

(56) **References Cited**

OTHER PUBLICATIONS

Starkhammer, H et al, Central Venous Catheter Placement using Electromagnetic Position Sensing: A Clinical Evaluation, Biomed. Instrum Technol, vol. 30 No. 2, pp. 164-170; Mar.-Apr. 1996.
Starr, David S et al, EKG Guided Placement of Subclavian CVP Catheters Using J-Wire, pp. 673-676, Ann. Surg, Dec. 1986.
Stas, M et al, Peroperative Intravasal Electrographic Control of Catheter Tip Position in Access Ports Placed by Venous Cut-Down Technique, EJSO, pp. 316-320, vol. 27, 2001.
Stereotaxis Magetic Navigation System with Navigant™ User Interface, 2005 Brochure.
Stereotaxis, Expanding the Possibilites of Interventional Medicine: Remote Navigation and Automation, pp. 1-8, Apr. 2011.
Tepa® Health Innovation PC based ECG System Introduction and Technical Specifications, EKG Master 1988 USB, 2 pages, Nov. 2003.
The FloWire Doppler Guide Wire located <http://www.volcanocorp.com/products/flowire-doppler-guide-wire.php>, 2011.
Traxal Technologies, Tracking Technology website overview: www.traxal.com/rd/rd_classroom_trackingtechnology.htm, last accessed Dec. 1, 2006.
UAB Health Systems, Arrhythmias, retrieved from http://www.health,uab.edu/14564/ on Nov. 15, 2007, 12 pages.
U.S. Appl. No. 11/466,602, filed Aug. 23, 2006 Advisory Action dated Jun. 22, 2009.
U.S. Appl. No. 11/466,602, filed Aug. 23, 2006 Final Office Action dated Apr. 8, 2010.
U.S. Appl. No. 11/466,602, filed Aug. 23, 2006 Final Office Action dated Jan. 30, 2009.
U.S. Appl. No. 11/466,602, filed Aug. 23, 2006 Non-Final Office Action dated Sep. 25, 2009.
U.S. Appl. No. 11/552,094, filed Oct. 23, 2006 Notice of Allowability dated Apr. 2, 2010.
U.S. Appl. No. 11/552,094, filed Oct. 23, 2006 Non-Final Office Action dated Apr. 27, 2009.
U.S. Appl. No. 11/552,094, filed Oct. 23, 2006 Notice of Allowance dated May 20, 2010.
U.S. Appl. No. 12/104,253, filed Apr. 16, 2008 Final Office Action dated Jul. 27, 2011.
U.S. Appl. No. 12/104,253, filed Apr. 16, 2008 Non-Final Office Action dated Nov. 29, 2010.
U.S. Appl. No. 12/323,273, filed Nov. 25, 2008 Non-Final Office Action dated Jun. 8, 2012.
U.S. Appl. No. 12/369,625, filed Feb. 11, 2009 Final Office Action dated Feb. 23, 2012.
U.S. Appl. No. 12/369,625, filed Feb. 11, 2009 Non-Final Office Action dated Jul. 20, 2011.
U.S. Appl. No. 12/427,244, filed Apr. 21, 2009 Non-Final Office Action dated Jan. 19, 2012.
U.S. Appl. No. 12/557,401, filed Sep. 10, 2009 Non-Final Office Action dated Apr. 24, 2012.
U.S. Appl. No. 12/878,915, filed Sep. 9, 2010 Non-Final Office Action dated Mar. 15, 2012.
Valdivieso, J.R. Perez, et al., Evaluation of a formula for optimal positioning of a central venous catheter inserted through the right internal jugular vein, Rev. Esp. Anestesiol. Reanim. 2003; 50: 77-79.
VasoNova Inc, Vascular navigation system for accurate placement of PICCs, Start-Up Emerging Medical Ventures, pp. 44-45, vol. 14 No. 7, Jul.-Aug. 2009.
Vesely, Thomas M. et al., Central Venous Catheter Tip Position: A Continuing Controversy, J Vasc Intery Radiol 2003; 14:527-534.
Viasys Health Care Inc. Cortrak© Fact Sheet, 2005.
Viasys Healthcare MedSystems, Navigator® Benefits, 2008.
Viasys Healthcare MedSystems, Navigator® Research in Cost Justification, 2008.
Viasys MedSystems, Cortrak™ Systems Brochure, 2005.
Volcano ComboMap Features and Benefits/Technical Specifications, 2 pages, 2011.
Watters, et al. "Use of Electrocardiogram to Position Right Atrial Catheters During Surgery." Annals of Surgery, vol. 225, No. 2, pp. 165-171, 1997.
Welch Allyn Cardioperfect® PC-Based Resting ECG, 2003.
Wilson, R. G. et al, Right Atrial Electrocardiography in Placement of Central Venous Catheters, The Lancet, pp. 462-463, Feb. 27, 1988.
Wong, Jeffrey J. et al., Azygos Tip Placement for Hemodialysis Catheters in Patients with Superior Vena Cava Occlusion, Cardiovasc Intervent Radiol (2006) 29:143-146.
Worley, Seth J. "Use of a Real-Time Three-Dimensional Magenetic Navigation System for Radiofrequency Ablation of Accessory Pathways." PACE, vol. 21 pp. 1636-1643, Aug. 1998.
Yilmazlar A et al, Complications of 1303 Central Venous Cannulations, J R Soc Med, pp. 319-321, vol. 90 No. 6, Jun. 1997 (Abstract only).
Yoon, SZ et al, Usefulness of the Carina as a Radiographic Landmark for Central Venous Catheter Placement in Paediatric Patients, Br J Anaesth, Jul. 2005.
Yoshida, Teruhisa et al, Detection of Concealed Left Sided Accessory Atrioventricular Pathway by P Wave Signal Averaged Electrocardiogram, J Am Coll Cardiol, pp. 55-62, 1999.
Zaaroor, et al. "Novel Magnetic Technology for Intraoperative Intracranial Frameless Navigation: In Vivo and in Vitro Results." Neurosurgery, vol. 48, No. 5. pp. 1100-1107, May 2001.
Zachariou, Zacharias et al., Intra-atrial ECG recording: a new and safe method for implantation of Broviac catheters in children, Pediatr Surg Int (1994) 9: 457-458.
DELTEC Cath-Finder® Tracking System Operation Manual, 1994.
Egelhof, Petra, Effects of Somatostatin on Portal Blood Flow and Portal Vein Pressure in Patients with Portal Hypertension due to Liver Cirrhosis Invasive Monitoring during TIPSS Procedures, Dissertation submitted to: Technical University of Munich, Faculty of Medicine, May 13, 2002; Date of examination: Feb. 26, 2003.
Engelhardt, W et al, ECG-Controlled Placement of Central Venous Catheters in Patients with Atrial Fibrallation, Anaesthesist, pp. 476-479, vol. 38 No. 9, Sep. 1989 (Abstract only).
EP 09808901.4 filed Aug. 21, 2009 European Search Report dated May 23, 2012.
EP 09813632.8 filed Apr. 5, 2011 European Search Report dated Jul. 4, 2012.
Fearon, William F et al, Evaluating Intermediate Coronary Lesions in the Cardiac Catheterization Laboratory, vol. 4, No. 1, 7 pages, Reviews in Cardiovascular Medicine, 2003.
Felleiter P et al, Use of Electrocardiographic Placement Control of Central Venous Catheters in Austria, Acta Med Austriaca, pp. 109-113, vol. 26 No. 3, 1999 (Abstract only).
Forauer, AR et al, Change in Peripherally Inserted Central Catheter Tip Location with Abduction and Adduction of the Upper Extremity, J Vasc Interv Radiol, pp. 1315-1318, vol. 11 No. 10, Nov.-Dec. 2000.
Frassinelli, P et al, Utility of Chest Radiographs after Guidewire Exchanges of Central Venous Catheters, Crit Care Med, pp. 611-615, vol. 26 No. 3, Mar. 1998.
Frazin L et al, A Doppler Guided Retrograde Catheterization System, Cathet. Cardiovasc Diagn, pp. 41-50, May 1992.
French, PJ et al, Sensors for Catheter Applications, Sensors Update, vol. 13 Issue 1 pp. 107-153, Dec. 2003.
GB Application 0800474.9 filed Aug. 24, 2006 Office Action dated Aug. 9, 2010.
GB Application 0800474.9 filed Aug. 24, 2006 Office Action dated Mar. 17, 2010.
Gebauer, B et al, Ultrasound and Fluoroscopy-guided Implantation of Peripherally Inserted Central Venous Catheters (PICCs), ROFO, pp. 386-391, vol. 176 No. 3, Mar. 2004 (Abstract only).
Gebhard, et al., "The accuracy of Electrocardiogram-Controlled Central Line Placement." The International Anesthesia Research Society, vol. 104, No. 1 Jan. 2007.
Gjendemsjo, Anders, et al., Energy and Power, The Connexions Project, Version 1.2, Feb. 20, 2004.
Gladwin, MT et al, Cannulation of the Internal Jugular Vein: is postpocedural chest radiography always necessary?, Crit Care Med, 33 pages, Oct. 2000.

(56) **References Cited**

OTHER PUBLICATIONS

Gonzales, et al. "Peripherally Inserted Central Catheter Placement in Swine Using Magnet Detection." Journal of Intravenous Nursing, vol. 22, No. 3, May/Jun. 1999.
Greenall, M.J. et al, Cardiac Tamponade and Central Venous Catheters, British Medical Journal, pp. 595-597, Jun. 14, 1975.
Guillory, "Basic Principles of Technologies for Catheter Localization." C.R. Bard internal paper, Oct. 20, 2004.
Guth, AA, Routine Chest X-rays after Insertion of Implantable Long-Term Venous Catheters: Necessary or Not?, Am Surg, pp. 26-29, vol. 67 No. 1, Jan. 2001 (Abstract only).
Hill, Bradley et al, Abstract of article discussing VasaNova VPS as guide for placement of PICCs. 2009.
Hill, Bradley, Identifying the Caval-Atrial Junction Using Smart-Catheter Technology presentation, 22nd Annual Scientific Meeting of the AVA in Savannah, Georgia, Sep. 13, 2008.
Hoffman, Thomas et al, Simultaneous Measurement of Pulmonary Venous Flow by Intravascular Catheter Doppler Velocimetry and Transesophageal Doppler Echocardiography: Relation to Left Atrial Pressure and Left Atrial and Left Ventricular Function, pp. 239-249, J Am Coll Cardiol, Jul. 1995.
Hoffmann, et al. "New Procedure in Transesophageal Echocardiography: Multiplane Transesophageal Echocardiography and Transesophageal Stress Echocardiography." Herz, vol. 18, No. 5, pp. 269-277, Oct. 1993.
Iacopino, Domenico Gerardo et al, Intraoperative Microvascular Doppler Monitoring of Blood Flow within a Spinal Dural Arteriovenous Fistula: A Precious Surgical Tool, vol. 10, 5 pages, Neurosurg. Focus, Feb. 2001.
Joosting, Jean-Pierre, "Dual-interface RFID-compatible EEPROM enables remote access to electronic device parameters," EE Times, Mar. 8, 2010.
JP 2008-528151 filed Aug 24, 2006 Notice of Grant dated May 6, 2012.
JP 2010-504220 filed Sep. 3, 2009 Office Action dated May 21, 2012.
Kim, Ko et al, Positioning Internal Jugular Venous Catheters using the Right Third Intercostal Space in Children, Acta Anaesthesiol Scand, pp. 1284-1286, vol. 47 No. 10, Nov. 2003.
Kjelstrup T et al, Positioning of Central Venous Catheters using ECG, Tidssk Nor Laegeforen, pp. 599-601, vol. 111 No. 5, Feb. 1999 (Abstract only).
Kofler, Julia, et al., Epinephrine application via an endotracheal airway and via the Combitube in esophageal position, Critical Care Medicine: May 2000, vol. 28: Issue 5, pp. 1445-1449.
Kowalski, CM et al, Migration of Central Venous Catheters: Implications for Initial Catheter Tip Positioning, J Vasc Interv Radiol, pp. 443-447, vol. 8 No. 3, May-Jun. 1997.
Leowenthal, MR et al, The Peripherally Inserted Central Catheter (PICC): A Prospective Study of its Natural History after Fossa Insertion, Anaesth Intensive Care, pp. 21-24; vol. 30 No. 1, Feb. 2002.
Lepage Ronan et al. ECG Segmentation and P-wave Feature Extraction: Application to Patients Prone to Atrial Fibrillation, IEEE/EMBS Proceedings, 23rd Annual Conference, Istanbul, Turkey, Oct. 25-28, 2001.
Liu , Ji-Bin et al, Catheter-Based Intralumincal Sonography, J Ultrasound Med, pp. 145-160, vol. 23, 2004.
Lucey, B et al, Routine Chest Radiographs after Central Line Insertion: Mandatory Postprocedural Evaluation or Unnecessary Waste of Resources?, Cardiovasc Intervent Radiol, pp. 381-384, vol. 22 No. 5, Sep.-Oct. 1999.
Lum, Phillip, A New Formula-Based Measurement Guide for Optimal Positioning of Central Venous Catheters, JAVA, vol. 9, No. 2, pp. 80-85, 2004.
Lynch, RE et al, A Procedure for Placing Pediatric Femoral Venous Catheter Tips near the Right Atrium, Pediatr Emerg Care, pp. 130-132, vol. 18 No. 2, Apr. 2002.
Madan, et al. "Right Atrial Electrocardiography: A Technique for the Placement of Central Venous Catheters for Chemotherapy or Intravenous Nutrition." British Journal of Surgery, vol. B1, pp. 1604-1605, 1994.
Madias, John E, Intracardiac (Superior Vena Cava/Right Atrial) ECGs using Saline Solution as the Conductive Medium for the Proper Positioning of the Shiley Hemodialysis Catheter: Is it Not Time to Forego the Postinsertion Chest Radiograph?, pp. 2363-2367, Chest, 2003.
Markovich, Mary B., Central Venous Catheter Tip Placement: Determination of Posterior Malposition—A Case Study, JAVA, vol. 11, No. 2, pp. 85-89, 2006.
Martin, Roy W, An Ultrasoundic Catheter for Intravascular Measurement of Blood Flow: Technical Details, IEEE Transactions on Sonics and Ultrasonics, vol. SU-27, No. 6, pp. 277-286, Nov. 1980.
McDonnall, "Intra-Atrial Electrocardiography (ECG) for Catheter Placement." Literature review prepared for Bard Access Systems, Oct. 2007.
McGee et al., "Accurate Placement of Central Venous Catheters: A Prospective, Randomize, Multicenter Trail." Critical Care Medicine, vol. 21 No. 8, Aug. 1993.
MedGraphics, CardioPerfect® Resting/Stress ECG System, 3 pages, 2001.
Michenfelder, John et al, Air Embolism During Neurosurgery—An Evaluation of Right-Atrial Catheters for Diagnosis and Treatment, JAMA, pp. 1353-1358, vol. 208, No. 8, May 26, 1969.
Michenfelder, John et al, Air Embolism During Neurosurgery. A New Method of Treatment, Anesthesia and Analgesia. Current Researches, pp. 390-395, vol. 45, No. 4, Jul.-Aug. 1966.
Microbird™ Miniaturized DC Magnetic Sensors for Intra-body Navigation and Localization, Specifications, 2005.
Micronix CathRite™ Cardiac Access Device Brochure. Jun. 2004.
CN 200880125528.4 filed Nov. 25, 2008 First Office Action dated Jun. 5, 2012.
EP 08855396.1 filed Jun. 15, 2010 European Search Report dated Jul. 31, 2012.
Konings, MK, et al., Development of an intravascular impedance catheter for detection of fatty lesions in arteries, IEEE Trans Med Imaging Aug. 1997; 16(4):439-46.
PCT/US2011/058138 filed Oct. 27, 2011 International Search Report dated Feb. 7, 2012.
PCT/US2011/058138 filed Oct. 27, 2011 Written Opinion dated Feb. 7, 2012.
PCT/US2012/045814 filed Jul. 6, 2012 International Search Report and Written Opinion dated Oct. 1, 2012.
Pop, Gheorghe A. et al., Catheter-based impedance measurements in the right atrium for continuously monitoring hematocrit and estimating blood viscosity changes; an in vivo feasibility study in swine, Biosensors and Bioelectronics 19 (2004) 1685-1693.
U.S. Appl. No. 11/466,602, filed Aug. 23, 2006 Appeal Board Decision dated Sep. 17, 2012.
U.S. Appl. No. 12/369,625, filed Feb. 11, 2009 Notice of Allowance dated Oct. 5, 2012.
U.S. Appl. No. 12/545,762, filed Aug. 21, 2009 Non-Final Office Action dated Aug. 1, 2012.
U.S. Appl. No. 12/715,556, filed Mar. 2, 2010 Non-Final Office Action dated Sep. 13, 2012.
U.S. Appl. No. 12/878,915, filed Sep. 9, 2010 Final Office Action dated Sep. 26, 2012.
U.S. Appl. No. 13/118,138, filed May 27, 2011 Non-Final Office Action dated Oct. 3, 2012.
U.S. Appl. No. 13/213,622, filed Aug. 19, 2011 Non-Final Office Action dated Jul. 31, 2012.
U.S. Appl. No. 13/336,919, filed Dec. 23, 2011 Non-Final Office Action dated Oct. 16, 2012.
U.S. Appl. No. 12/854,083, filed Aug. 10, 2010 Final Office Action dated Aug. 15, 2013.
U.S. Appl. No. 12/854,083, filed Aug. 10, 2010 Non-Final Office Action dated Jan. 29, 2013.
U.S. Appl. No. 12/854,083, filed Aug. 10, 2010 Non-Final Office Action dated Jan. 29, 2014.
U.S. Appl. No. 12/878,915, filed Sep. 9, 2010 Notice of Allowance dated Jan. 8, 2013.

(56) **References Cited**

OTHER PUBLICATIONS

U.S. Appl. No. 12/893,916, filed Sep. 29, 2010 Non-Final Office Action dated Dec. 24, 2013.
U.S. Appl. No. 12/900,750, filed Oct. 8, 2010 Non-Final Office Action dated Jun. 3, 2013.
U.S. Appl. No. 13/019,939, filed Feb. 2, 2011 Non-Final Office Action dated Oct. 11, 2013.
U.S. Appl. No. 13/118,138, filed May 27, 2011 Final Office Action dated Apr. 3, 2013.
U.S. Appl. No. 13/118,138, filed May 27, 2011 Final Office Action dated Aug. 1, 2013.
U.S. Appl. No. 13/213,622, filed Aug. 19, 2011 Final Office Action dated Feb. 19, 2013.
U.S. Appl. No. 13/283,395, filed Oct. 27, 2011 Non-Final Office Action dated Apr. 23, 2013.
U.S. Appl. No. 13/336,919, filed Dec. 23, 2011 Advisory Action dated May 23, 2013.
U.S. Appl. No. 13/336,919, filed Dec. 23, 2011 Final Office Action dated Mar. 1, 2013.
U.S. Appl. No. 13/336,919, filed Dec. 23, 2011 Non-Final Office Action dated Dec. 27, 2013.
U.S. Appl. No. 13/337,987, filed Dec. 27, 2011 Non-Final Office Action dated Mar. 15, 2013.
U.S. Appl. No. 13/665,420, filed Oct. 31, 2012 Non-Final Office Action dated Jan. 6, 2014.
U.S. Appl. No. 29/428,649, filed Aug. 1, 2012 Notice of Allowance dated Jul. 5, 2013.
AU 2008329807 exam requested Aug. 13, 2012 Examination Report No. 1 dated Feb. 15, 2013.
AU 2008329807 exam requested Aug. 13, 2012 Notice of Acceptance dated Feb. 14, 2014.
AU 2011289513 filed Jan. 21, 2013 Examiner's Report dated Jul. 5, 2013.
AU 2012202293 filed Apr. 19, 2012 Examination Report No. 1 dated Apr. 24, 2013.
AU 2013201648 filed Mar. 19, 2013 Examiner's Report dated Mar. 5, 2014.
AU 2013201648 filed Mar. 19, 2013 Examiner's Report dated Oct. 14, 2013.
AU 2013204243 filed Apr. 12, 2013 Examiner's Report dated Jun. 5, 2013.
CA 2,619,909 filed Aug. 24, 2006 Examiner's Report dated Oct. 26, 2012.
CN 200880012117.4 filed Apr. 16, 2008 Second Office Action dated Oct. 8, 2012.
CN 200880012117.4 filed Apr. 16, 2008 Third Office Action dated Apr. 27, 2013.
CN 200880125528.4 filed Nov. 25, 2008 Second Office Action dated Mar. 6, 2013.
CN 200880125528.4 filed Nov. 25, 2008 Third Office Action dated Jul. 1, 2013.
CN 200980123021.X filed Dec. 17, 2010 First Office Action dated Nov. 19, 2012.
CN 200980123021.X filed Dec. 17, 2010 Second Office Action dated Aug. 13, 2013.
CN 200980144663.8 filed May 9, 2011 First Office Action dated Dec. 5, 2012.
CN 200980144663.8 filed May 9, 2011 Second Office Action dated Aug. 22, 2013.
EP 08855396.1 filed Jun. 15, 2010 Intent to Grant dated Jul. 5, 2013.
EP 09707467.8 supplemental European search report dated Jun. 18, 2013.
EP 09808901.4 filed Aug. 21, 2009 Examination Report dated May 10, 2013.
EP 09813632.8 filed Apr. 5, 2011 Office Action dated Apr. 30, 2013.
EP 12177438.4 filed Jul. 23, 2012 Communication dated Jan. 13, 2014.
EP 12177438.4 filed Jul. 23, 2012 European Search Report dated Dec. 4, 2012.
EP 12177438.4 filed Jul. 23, 2012 extended European Search Report dated Mar. 25, 2013.
JP 2010-504220 filed Sep. 3, 2009 Final Office Action dated Apr. 18, 2013.
JP 2010-535117 filed May 26, 2011 First Office Action dated Aug. 5, 2013.
PCT/US13/62409 filed Sep. 27, 2013 International Search Report and Written Opinion dated Feb. 24, 2014.
PCT/US2011/038391 filed May 27, 2011 International Preliminary Report on Patentability and Written Opinion dated Dec. 4, 2012.
PCT/US2011/038391 filed May 27, 2011 International Search Report dated Sep. 21, 2011.
PCT/US2011/038415 filed May 27, 2011 International Preliminary Report on Patentability dated Dec. 13, 2012.
PCT/US2011/047127 filed Aug. 9, 2011 International Preliminary Report on Patentability dated Apr. 18, 2013.
PCT/US2011/052793 filed Sep. 22, 2011 International Preliminary Report on Patentability dated Apr. 4, 2013.
PCT/US2011/058138 filed Oct. 27, 2011 International Preliminary Report on Patentability dated May 10, 2013.
PCT/US2011/067268 filed Dec. 23, 2011 International Preliminary Report on Patentability dated Jul. 4, 2013.
PCT/US2013/065121 filed Oct. 15, 2013 International Search Report and Written Opinion dated Jan. 16, 2014.
U.S. Appl. No. 11/466,602, filed Aug. 23, 2006 Final Office Action dated Oct. 28, 2013.
U.S. Appl. No. 11/466,602, filed Aug. 23, 2006 Non-Final Office Action dated Mar. 28, 2013.
U.S. Appl. No. 11/466,602, filed Aug. 23, 2006 Notice of Allowance dated Dec. 3, 2012.
U.S. Appl. No. 11/466,602, filed Aug. 23, 2006 Notice of Allowance dated Mar. 14, 2014.
U.S. Appl. No. 12/426,175, filed Apr. 17, 2009 Advisory Action dated Nov. 26, 2013.
U.S. Appl. No. 12/426,175, filed Apr. 17, 2009 Final Office Action dated Aug. 2, 2013.
U.S. Appl. No. 12/426,175, filed Apr. 17, 2009 Final Office Action dated Jan. 31, 2014.
U.S. Appl. No. 12/426,175, filed Apr. 17, 2009 Non-Final Office Action dated Dec. 3, 2012.
U.S. Appl. No. 12/545,762, filed Aug. 21, 2009 Final Office Action dated Mar. 7, 2013.
U.S. Appl. No. 12/545,762, filed Aug. 21, 2009 Non-Final Office Action dated Dec. 13, 2013.
U.S. Appl. No. 12/557,401, filed Sep. 10, 2009 Non-Final Office Action dated Jan. 6, 2014.
U.S. Appl. No. 12/575,456, filed Oct. 7, 2009 Non-Final Office Action dated Oct. 5, 2012.
U.S. Appl. No. 12/715,556, filed Mar. 2, 2010 Final Office Action dated Oct. 2, 2013.
U.S. Appl. No. 12/815,331, filed Jun. 14, 2010 Advisory Action dated Oct. 4, 2013.
U.S. Appl. No. 12/815,331, filed Jun. 14, 2010 Final Office Action dated Jul. 26, 2013.
U.S. Appl. No. 12/815,331, filed Jun. 14, 2010 Non-Final Office Action dated Jan. 22, 2013.
AU 2010300677 filed Mar. 12, 2012 First Examination Report dated Mar. 9, 2014.
AU 2013202824 filed Apr. 6, 2013 First Examiner's Report dated Mar. 10, 2014.
Benzadon, M. N. et al: "Comparison of the Amplitude of the P-Wave from Intracardiac Electrocardiogram Obtained by Means of a Central Venous Catheter Filled With Saline Solution to That Obtained Via Esophageal Electrocardiogram", American Journal of Cardiology, Cahners Publishing Co., Newton, MA, US, vol. 98, No. 7, Oct. 1, 2006 (Oct. 1, 2006), pp. 978-981.
CN 200980123021.X filed Dec. 17, 2010 Third Office Action dated Apr. 22, 2014.
CN 200980144663.8 filed May 9, 2011 Third Office Action dated May 4, 2014.
CN 201080035659.0 filed Feb. 10, 2012 First Office Action dated Jan. 26, 2014.

(56) **References Cited**

OTHER PUBLICATIONS

CN 201080053838.7 filed May 28, 2012 First Office Action dated Jan. 6, 2014.
CN 201080053838.7 filed May 28, 2012 Second Office Action dated Jun. 17, 2014.
CN 201180016462.7 filed Sep. 27, 2012 First Office Action dated Mar. 21, 2014.
EP 09813632.8 filed Apr. 5, 2011 Summons to Attend Oral Proceedings dated Apr. 16, 2014.
EP 10 808 660.4 filed Feb. 15, 2012 Extended European Search Report dated Mar. 4, 2014.
EP 10786978.6 filed Dec. 19, 2011 Extended European Search Report dated Mar. 7, 2014.
EP 13194818.4 filed Nov. 28, 2013 extended European search report dated Feb. 28, 2014.
EP 14151268.1 filed Jan. 15, 2014 European Search Report dated Feb. 21, 2014.
Jeon, Yunseok et al., "Transesophageal Echocardiographic Evaluation of ECG-guided Central Venous Catheter Placement," Canadian Journal of Anesthesia, vol. 53, No. 10, Oct. 1, 2006, pp. 978-983.
JP 2012-515222 filed Dec. 9, 2011 Office Action dated Mar. 24, 2014.
PCT/US2009/041051 filed Apr. 17, 2009 International Preliminary Report on Patentability dated Apr. 8, 2014.
PCT/US2011/048403 filed Aug. 19, 2011 International Preliminary Report on Patentability dated Jul. 30, 2013.
PCT/US2014/022019 filed Mar. 7, 2014 International Search Report and Written Opinion dated Jun. 11, 2014.
RU 2011150917 filed Dec. 15, 2011 First Office Action dated Apr. 24, 2014.
RU 2011150917 filed Dec. 15, 2011 Second Office Action dated Aug. 28, 2014.
U.S. Appl. No. 12/815,331, filed Jun. 14, 2010 Non-Final Office Action dated Jul. 2, 2014.
U.S. Appl. No. 12/854,083, filed Aug. 10, 2010 Advisory Action dated Sep. 8, 2014.
U.S. Appl. No. 12/854,083, filed Aug. 10, 2010 Final Office Action dated Jul. 1, 2014.
U.S. Appl. No. 12/893,916, filed Sep. 29, 2010 Advisory Action dated Aug. 15, 2014.
U.S. Appl. No. 12/893,916, filed Sep. 29, 2010 Final Office Action dated Jun. 18, 2014.
U.S. Appl. No. 12/893,916, filed Sep. 29, 2010 Non-Final Office Action dated Sep. 25, 2014.
U.S. Appl. No. 13/019,939, filed Feb. 2, 2011 Final Office Action dated Apr. 2, 2014.
U.S. Appl. No. 13/118,033, filed May 27, 2011 Non-Final Office Action dated May 22, 2014.
U.S. Appl. No. 13/118,138, filed May 27, 2011 Non-Final Office Action dated Oct. 9, 2014.
U.S. Appl. No. 13/213,622, filed Aug. 19, 2011 Non-Final Office Action dated May 22, 2014.
U.S. Appl. No. 13/737,806, filed Jan. 9, 2013 Notice of Allowance dated Oct. 31, 2013.
U.S. Appl. No. 13/887,166, filed May 3, 2013 Advisory Action dated Aug. 27, 2014.
U.S. Appl. No. 13/887,166, filed May 3, 2013 Final Office Action dated Jun. 23, 2014.
U.S. Appl. No. 13/887,166, filed May 3, 2013 Non-Final Office Action dated Jan. 7, 2014.
U.S. Appl. No. 13/890,158, filed May 8, 2013 Non-Final Office Action dated Aug. 15, 2014.
U.S. Appl. No. 13/969,265, filed Aug. 16, 2013 Non-Final Office Action dated Dec. 19, 2013.
U.S. Appl. No. 13/969,265, filed Aug. 16, 2013 Notice of Allowance dated Jun. 23, 2014.
U.S. Appl. No. 14/141,046, filed Dec. 26, 2013 Non-Final Office Action dated Jun. 20, 2014.
U.S. Appl. No. 14/317,501, filed Jun. 27, 2014 Non-Final Office Action dated Sep. 12, 2014.
Zaidi, Naveed A., et al. "Room temperature magnetic order in an organic magnet derived from polyaniline." 2004, Polymer, vol. 45, pp. 5683-5689.
CA 2,721,715 filed Apr. 17, 2009 Examiner's Report dated Aug. 18, 2015.
CN 200980144663.8 filed May 9, 2011 Fifth Office Action dated May 26, 2015.
CN 200980144663.8 filed May 9, 2011 Fourth Office Action dated Nov. 15, 2014.
CN 201080035659.0 filed Feb. 10, 2012 Second Office Action dated Oct. 9, 2014.
CN 201080035659.0 filed Feb. 10, 2012 Third Office Action dated Mar. 19, 2015.
CN 201080053838.7 filed May 28, 2012 Fourth Office Action dated Jun. 2, 2015.
CN 201080053838.7 filed May 28, 2012 Third Office Action dated Dec. 4, 2014.
CN 201180016462.7 filed Sep. 27, 2012 Second Office Action dated Dec. 9, 2014.
CN 201180016462.7 filed Sep. 27, 2012 Third Office Action dated Jun. 10, 2015.
CN 201180037065.8 filed Jan. 28, 2013 First Office Action dated Jun. 2, 2015.
CN 201180037065.8 filed Jan. 28, 2013 First Office Action dated Sep. 28, 2014.
CN 201180037068.1 filed Jan. 28, 2013 First Office Action dated Apr. 20, 2015.
CN 201180037068.1 filed Jan. 28, 2013 First Office Action dated Sep. 9, 2014.
CN 201180040151.4 filed Feb. 19, 2013 First Office Action dated Oct. 28, 2014.
CN 201180040151.4 filed Feb. 19, 2013 Second Office Action dated Jun. 19, 2015.
CN 201180043512.0 filed Mar. 8, 2013 First Office Action dated Jul. 31, 2014.
CN 201180043512.0 filed Mar. 8, 2013 Second Office Action dated Apr. 14, 2015.
CN 201180052587.5 filed Apr. 28, 2013 First Office Action dated Jan. 26, 2015.
CN 201180052587.5 filed Apr. 28, 2013 Second Office Action dated Aug. 19, 2015.
CN 201180068309.9 filed Aug. 22, 2013 First Office Action dated Oct. 16, 2014.
CN 201180068309.9 filed Aug. 22, 2013 Second Office Action dated May 6, 2015.
EP 10821193.9 filed Mar. 27, 2012 Partial European Search Report dated Oct. 9, 2015.
EP 11 818 828.3 filed Mar. 18, 2013 Extended European Search Report dated Dec. 10, 2014.
EP 11787515.3 filed Dec. 12, 2012 partial European search report dated Jun. 23, 2015.
EP 11787527.8 filed Dec. 19, 2012 Extended European Search Report dated Oct. 9, 2015.
EP 11787527.8 filed Dec. 19, 2012 partial European search report dated May 26, 2015.
EP 11837113.7 filed May 28, 2013 Extended European Search Report dated Apr. 24, 2014.
EP 12177438.4 filed Jul. 23, 2012 European Search Report dated Jun. 7, 2015.
EP 12177438.4 filed Jul. 23, 2012 Examination Report dated Dec. 5, 2014.
EP 12807886.2 filed Jan. 15, 2014 Extended European Search Report dated Feb. 6, 2015.
EP14197136.6 filed Dec. 10, 2014 Extended European Search Report dated May 26, 2015.
JP 2012-515222 filed Dec. 9, 2011 Office Action dated Feb. 23, 2015.
JP 2012-552060 filed Aug. 1, 2012 Office Action dated Nov. 12, 2014.
JP 2013-512046 filed Nov. 26, 2012 First Office Action dated Mar. 23, 2015.

(56) **References Cited**

OTHER PUBLICATIONS

JP 2013-512051 filed Nov. 26, 2012 First Office Action dated Mar. 23, 2015.
JP 2013-524999 filed Jan. 22, 2013 First Office Action dated Jun. 1, 2015.
Moureau, Nancy L. et al., "Electrocardiogram (EKG) Guided Peripherally Inserted Central Catheter Placement and Tip Position: Results of a Trial to Replace Radiological Confirmation," Journal of the Association for Vascular Access, pp. 8-14, vol. 15, No. 1, 2010.
MX/a/2012/013672 filed Nov. 23, 2012 First Office Action dated Aug. 10, 2015.
MX/a/2012/013858 filed Nov. 28, 2012 First Office Action dated Sep. 26, 2014.
MX/a/2012/013858 filed Nov. 28, 2012 Second Office Action dated Jun. 10, 2015.
PCT/US2015/014795 filed Feb. 6, 2015 International Search Report and Written Opinion dated May 14, 2015.
Pittiruti, et al, "The intracavitary ECG method for positioning the tip of central venous catheters: results of an Italian multicenter study," J Vasc Access, pp. 1-9, Nov. 21, 2011.
Pittiruti, et al. "The electrocardiographic method for positioning the tip of central venous catheters" JAVA, pp. 1-12, Feb. 12, 2011.
U.S. Appl. No. 1/118,033, filed May 27, 2011 Non-Final Office Action dated Jul. 8, 2015.
U.S. Appl. No. 12/426,175, filed Apr. 17, 2009 Examiner's Answer dated Oct. 7, 2014.
U.S. Appl. No. 12/545,762, filed Aug. 21, 2009 Non-Final Office Action dated Nov. 7, 2014.
U.S. Appl. No. 12/545,762, filed Aug. 21, 2009 Non-Final Office Action dated Sep. 11, 2015.
U.S. Appl. No. 12/815,331, filed Jun. 14, 2010 Advisory Action dated Mar. 5, 2015.
U.S. Appl. No. 12/815,331, filed Jun. 14, 2010 Final Office Action dated Dec. 23, 2014.
U.S. Appl. No. 12/815,331, filed Jun. 14, 2010 Non-Final Office Action dated Jun. 1, 2015.
CN 201180037068.1 filed Jan. 28, 2013 Third Office Action dated Oct. 19, 2015.
CN 201180040151.4 filed Feb. 19, 2013 Third Office Action dated Dec. 10, 2015.
CN 201180068309.9 filed Aug. 22, 2013 Third Office Action dated Sep. 2, 2015.
EP 11787515.3 filed Dec. 12, 2012 partial European search report dated Oct. 27, 2015.
JP 2012-552060 filed Aug. 1, 2012 Second Office Action dated Nov. 6, 2015.
JP 2013-512046 filed Nov. 26, 2012 Decision of Rejection dated Dec. 8, 2015.
U.S. Appl. No. 12/815,331, filed Jun. 14, 2010 Final Office Action dated Nov. 4, 2015.
U.S. Appl. No. 13/240,171, filed Sep. 22, 2011 Non-Final Office Action dated Dec. 1, 2015.
U.S. Appl. No. 14/141,046, filed Dec. 26, 2013 Non-Final Office Action dated Nov. 5, 2015.
U.S. Appl. No. 14/201,300, filed Mar. 7, 2014 Non-Final Office Action dated Jan. 6, 2016.
U.S. Appl. No. 14/449,061, filed Jul. 31, 2014 Final Office Action dated Nov. 6, 2015.
U.S. Appl. No. 12/854,083, filed Aug. 10, 2010 Final Office Action dated Aug. 21, 2015.
U.S. Appl. No. 12/854,083, filed Aug. 10, 2010 Non-Final Office Action dated Mar. 16, 2015.
U.S. Appl. No. 12/893,916, filed Sep. 29, 2010 Final Office Action dated Jan. 15, 2015.
U.S. Appl. No. 12/893,916, filed Sep. 29, 2010 Non-Final Office Action dated Sep. 10, 2015.
U.S. Appl. No. 13/019,939, filed Feb. 2, 2011 Non-Final Office Action dated Feb. 9, 2015.
U.S. Appl. No. 13/118,033, filed May 27, 2011 Non-Final Office Action dated Feb. 3, 2015.
U.S. Appl. No. 13/118,138, filed May 27, 2011 Non-Final Office Action dated Jul. 15, 2015.
U.S. Appl. No. 13/240,171, filed Sep. 22, 2011 Advisory Action dated Aug. 18, 2015.
U.S. Appl. No. 13/240,171, filed Sep. 22, 2011 Final Office Action dated Jun. 10, 2015.
U.S. Appl. No. 13/240,171, filed Sep. 22, 2011 Non-Final Office Action dated Dec. 26, 2014.
U.S. Appl. No. 13/283,395, filed Oct. 27, 2011 Advisory Action dated Jan. 28, 2014.
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U.S. Appl. No. 13/336,919, filed Dec. 23, 2011 Non-Final Office Action dated Jul. 9, 2015.
U.S. Appl. No. 13/665,420, filed Oct. 31, 2012 Non-Final Office Action dated Jul. 9, 2015.
U.S. Appl. No. 13/665,420, filed Oct. 31, 2012 Non-Final Office Action dated Oct. 9, 2014.
U.S. Appl. No. 13/887,166, filed May 3, 2013 Examiner's Answer dated Jul. 16, 2015.
U.S. Appl. No. 13/890,158, filed May 8, 2013 Non-Final Office Action dated Jul. 9, 2015.
U.S. Appl. No. 14/141,046, filed Dec. 26, 2013 Non-Final Office Action dated Feb. 11, 2015.
U.S. Appl. No. 14/270,241, filed May 5, 2014 Non-Final Office Action dated Apr. 23, 2015.
U.S. Appl. No. 14/270,241, filed May 5, 2014 Notice of Allowance dated Oct. 7, 2015.
U.S. Appl. No. 14/309,511, filed Jun. 19, 2014 Non-Final Office Action, dated Sep. 24, 2015.
U.S. Appl. No. 14/317,501, filed Jun. 27, 2014 Advisory Action dated Sep. 16, 2015.
U.S. Appl. No. 14/317,501, filed Jun. 27, 2014 Final Office Action dated Jul. 1, 2015.
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U.S. Appl. No. 14/506,552, filed Oct. 3, 2014 Non-Final Office Action dated Oct. 1, 2015.
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CN 201280033189.3 filed Jan. 3, 2014 First Office Action dated Apr. 3, 2014.
CN 201280033189.3 filed Jan. 3, 2014 Second Office Action dated Sep. 14, 2015.
CN 201410009216.4 filed Jan. 8, 2014 Second Office Action dated Sep. 25, 2015.
EP 09743249.6 filed Oct. 18, 2010 Extended European Search Report dated Jan. 13, 2016.
EP 11740309.7 filed Aug. 23, 2012 Extended European Search Report dated Aug. 3, 2015.
EP 15179061.5 filed Jul. 30, 2015 Extended European Search Report dated Jan. 14, 2016.
JP2013-530322 filed Mar. 18, 2013, First Office Action dated Jul. 31, 2015.
MX/a/2013/001317 filed Jan. 31, 2013 First Office Action dated Nov. 26, 2015.
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CN 2011800525875 filed Apr. 28, 2013 Office Action dated Feb. 24, 2016.
U.S. Appl. No. 12/545,762, filed Aug. 21, 2009 Non-Final Office Action dated Feb. 16, 2016.
U.S. Appl. No. 12/893,916, filed Sep. 29, 2010 Final Office Action dated Mar. 25, 2016.
U.S. Appl. No. 13/118,033, filed May 27, 2011 Final Office Action dated Apr. 1, 2016.

(56) **References Cited**

OTHER PUBLICATIONS

U.S. Appl. No. 13/118,138, filed May 27, 2011 Final Office Action dated Apr. 1, 2016.
U.S. Appl. No. 13/240,171, filed Sep. 22, 2011 Final Office Action dated May 6, 2016.
U.S. Appl. No. 13/665,420, filed Oct. 31, 2012 Final Office Action dated Apr. 8, 2016.
U.S. Appl. No. 14/040,205, filed Sep. 27, 2013 Non-Final Office Action dated Mar. 10, 2016.
U.S. Appl. No. 14/201,300, filed Mar. 7, 2014 Final Office Action dated May 5, 2016.
U.S. Appl. No. 14/449,061, filed Jul. 31, 2014 Notice of Allowance dated Apr. 13, 2016.
U.S. Appl. No. 14/498,887, filed Sep. 26, 2014 Non-Final Office Action dated Feb. 19, 2016.
CN 200880012117.4 filed Apr. 16, 2008 Fourth Office Action dated Sep. 4, 2013.
JP 2010-504220 filed Sep. 3, 2009 Office Action dated Apr. 1, 2014.
JP 2010-504220 filed Sep. 3, 2009 Office Action dated Apr. 18, 2013.
U.S. Appl. No. 12/369,625, filed Feb. 11, 2009 Notice of Panel Decision dated Aug. 1, 2012.
U.S. Appl. No. 13/337,987, filed Dec. 27, 2011 Examiner's Answer dated Jul. 2, 2014.
U.S. Appl. No. 13/337,987, filed Dec. 27, 2011 Final Office Action dated Sep. 19, 2013.
U.S. Appl. No. 13/858,782, filed Apr. 8, 2013 Notice of Allowance dated Oct. 9, 2014.
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JP 2013-512046 filed Nov. 26, 2012 Office Action dated May 16, 2016.
JP 2014-519081 filed Dec. 27, 2013 First Office Action dated Apr. 26, 2016.
U.S. Appl. No. 14/141,046, filed Dec. 26, 2013 Final Office Action dated May 11, 2016.
AU 2012278809 filed Nov. 12, 2013 Notice of Acceptance dated Sep. 13, 2016.
CA 2,721,715 filed Apr. 17, 2009 Examiner's Report dated Oct. 25, 2016.
CN 200980144663.8 filed May 9, 2011 Notice of Reexamination dated Aug. 5, 2016.
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EP 13840356.3 filed Apr. 27, 2015 Partial European Search Report dated Oct. 19, 2016.
EP 13846380.7 filed May 15, 2015 Partial European Search Report dated Sep. 30, 2016.
EP 14761249.3 Filed Sep. 3, 2015 Extended European Search Report dated Sep. 19, 2016.
KR 10-2012-7000866 filed Jan. 11, 2012 Second Office Action dated Nov. 3, 2016.
PCT/US2016/039356 filed Jun. 24, 2016 International Search Report and Written Opinion dated Sep. 16, 2016.
U.S. Appl. No. 12/426,175, filed Apr. 17, 2009 Decision on Appeal dated Nov. 7, 2016.
U.S. Appl. No. 12/545,762, filed Aug. 21, 2009 Non-Final Office Action dated Sep. 26, 2016.
U.S. Appl. No. 12/893,916, filed Sep. 29, 2010 Non-Final Office Action dated Aug. 31, 2016.
U.S. Appl. No. 13/118,033, filed May 27, 2011 Notice of Allowance dated Sep. 2, 2016.
U.S. Appl. No. 14/040,205, filed Sep. 27, 2013 Final Office Action dated Oct. 19, 2016.
U.S. Appl. No. 14/054,700, filed Oct. 15, 2013 Final Office Action dated Oct. 19, 2016.
U.S. Appl. No. 14/548,151, filed Nov. 19, 2014 Non-Final Office Action dated Sep. 28, 2016.
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KR 10-2012-7000866 filed Jan. 11, 2012 First Office Action dated Jun. 16, 2016.
RU 2013158008 filed Dec. 26, 2013 First Office Action dated May 27, 2016.
U.S. Appl. No. 13/240,171, filed Sep. 22, 2011 Advisory Action dated Jul. 22, 2016.
U.S. Appl. No. 13/336,919, filed Dec. 23, 2011 Notice of Allowance dated Jul. 26, 2016.
U.S. Appl. No. 13/890,158, filed May 8, 2013 Advisory Action dated Jul. 26, 2016.
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U.S. Appl. No. 14/317,501, filed Jun. 27, 2014 Examiner's Answer dated Jun. 30, 2016.
U.S. Appl. No. 14/498,887, filed Sep. 26, 2014 Advisory Action dated Aug. 22, 2016.
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U.S. Appl. No. 14/548,151, filed Nov. 19, 2014 Advisory Action dated Jul. 22, 2016.
JP2013-530322 filed Mar. 18, 2013, Office Action dated May 2, 2016.
U.S. Appl. No. 12/893,916, filed Sep. 29, 2010 Advisory Action dated Jun. 2, 2016.
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CO 15110530 filed May 14, 2015 Office Action dated Nov. 25, 2016.
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U.S. Appl. No. 14/040,205 filed Sep. 27, 2013 Advisory Action dated Dec. 15, 2016.
U.S. Appl. No. 14/054,700 filed Oct. 15, 2013 Advisory Action dated Dec. 15, 2016.
U.S. Appl. No. 14/201,300 filed Mar. 7, 2014 Final Office Action dated Dec. 19, 2016.
U.S. Appl. No. 14/615,932 filed Feb. 6, 2015 Non-Final Office dated Dec. 29, 2016.
U.S. Appl. No. 14/846,496 filed Sep. 4, 2015 Non-Final Office Action dated Nov. 25, 2016.
U.S. Appl. No. 15/160,958 filed May 20, 2016 Non-Final Office Action dated Dec. 15, 2016.
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JP 2013-530322 filed Mar. 18, 2013, Office Action dated Mar. 2, 2017.
U.S. Appl. No. 13/665,420 filed Oct. 31, 2012 Non-Final Office Action dated Mar. 15, 2017.
U.S. Appl. No. 14/201,300 filed Mar. 7, 2014 Advisory Action dated Mar. 2, 2017.
U.S. Appl. No. 14/201,300 filed Mar. 7, 2014 Non-Final Office Action dated Mar. 30, 2017.

* cited by examiner

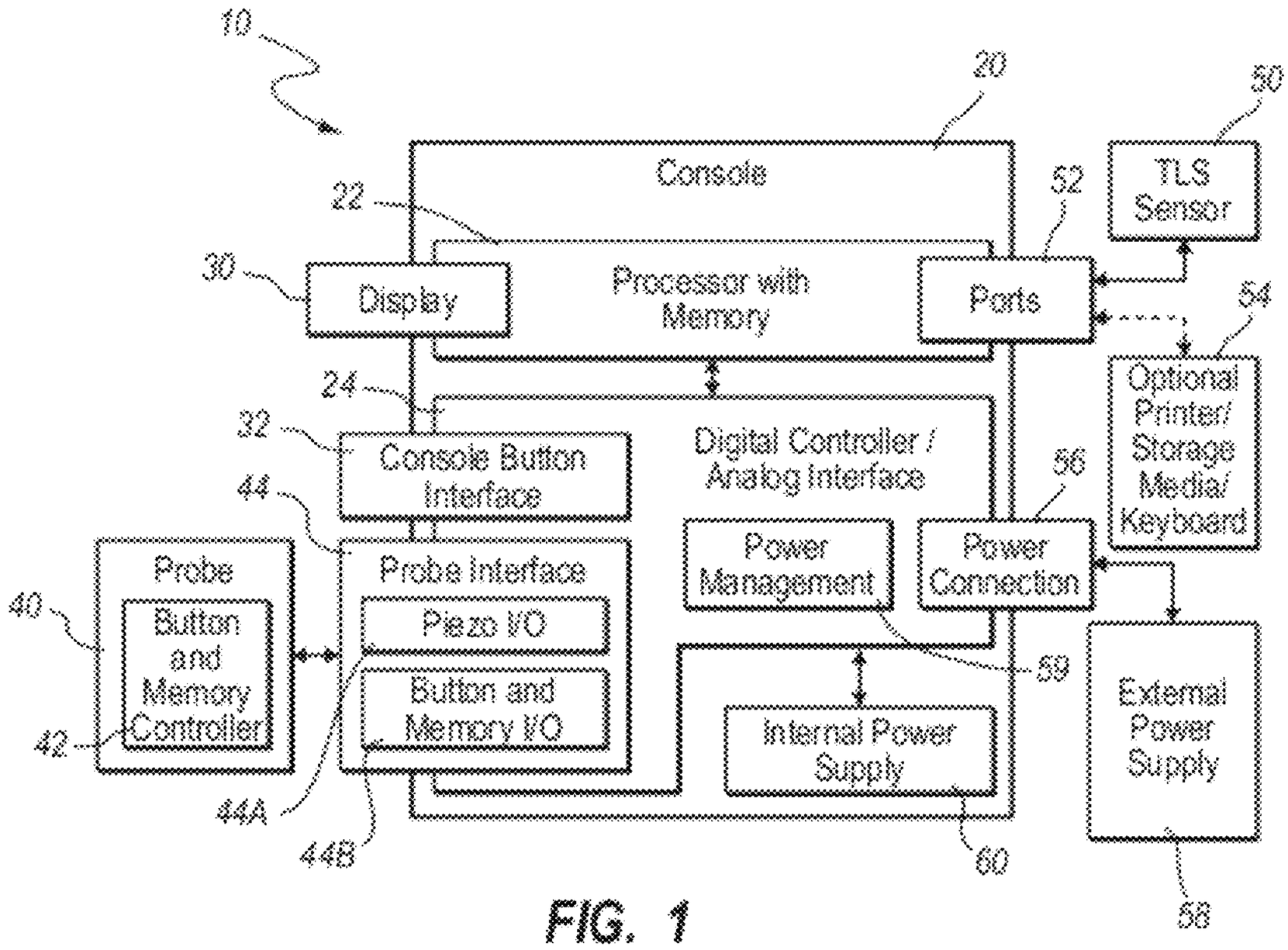
10
20
Console
50
TLS Sensor
52
22
30
Display
Processor with Memory
Ports
54
24
Optional Printer/ Storage Media/ Keyboard
32
Console Button Interface
Digital Controller / Analog Interface
56
44
Power Management
Power Connection
Probe
Probe Interface
40
Button and Memory Controller
Piezo I/O
59
External Power Supply
Button and Memory I/O
42
Internal Power Supply
44A
44B
60
58

FIG. 1

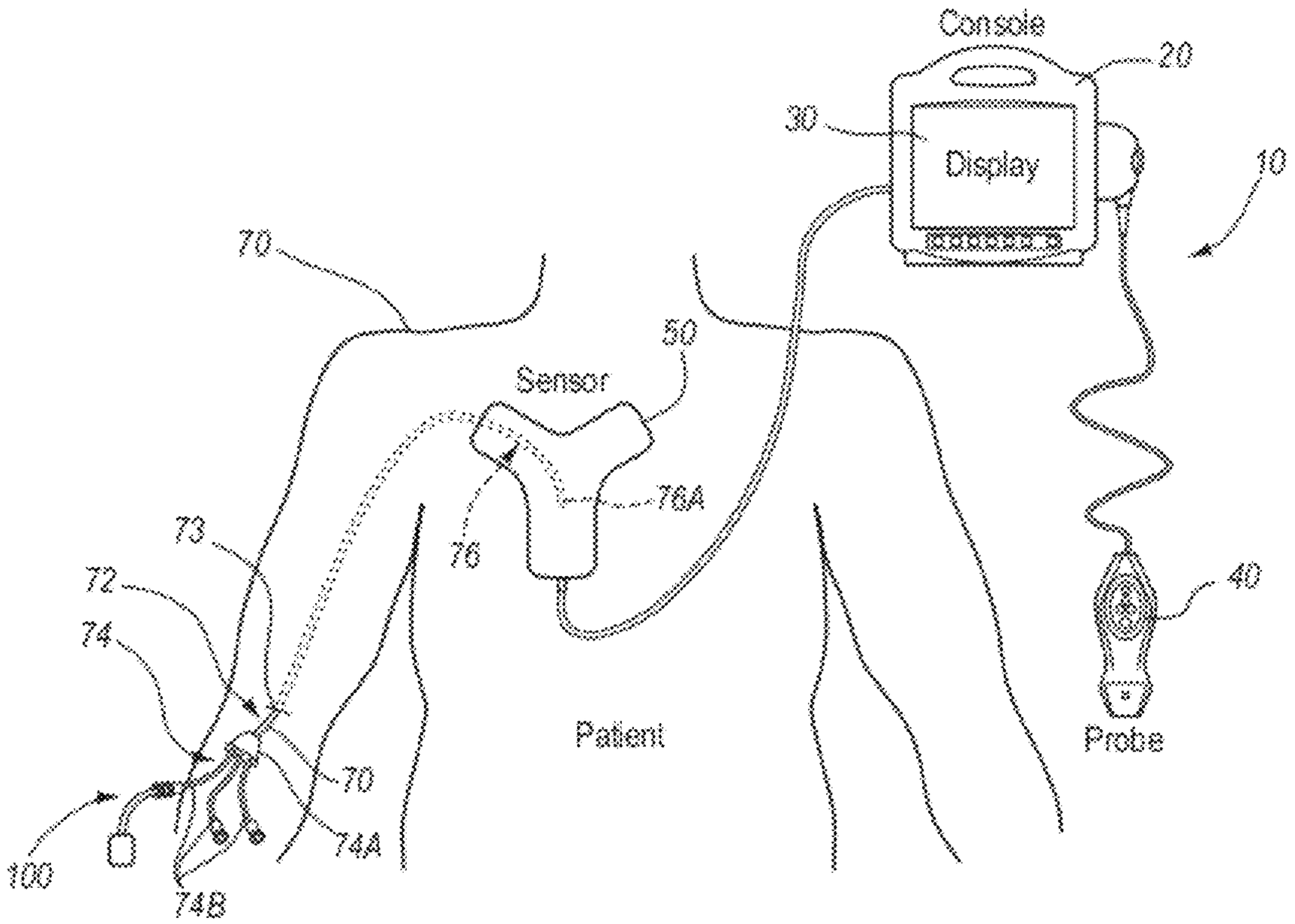
Console
20
30
Display
10
70
50
Sensor
76A
76
73
72
74
40
Patient
Probe
70
74A
100
74B

FIG. 2

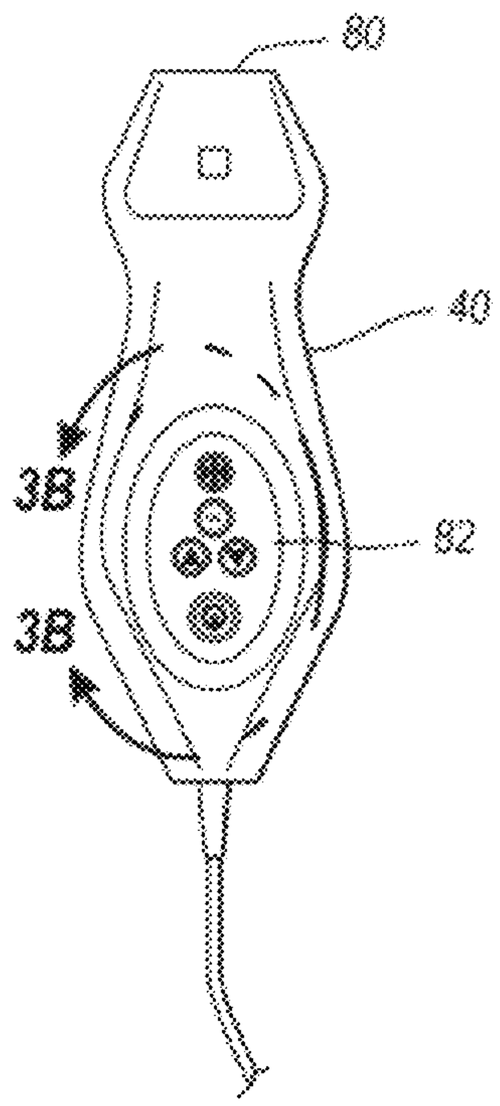

FIG. 3A

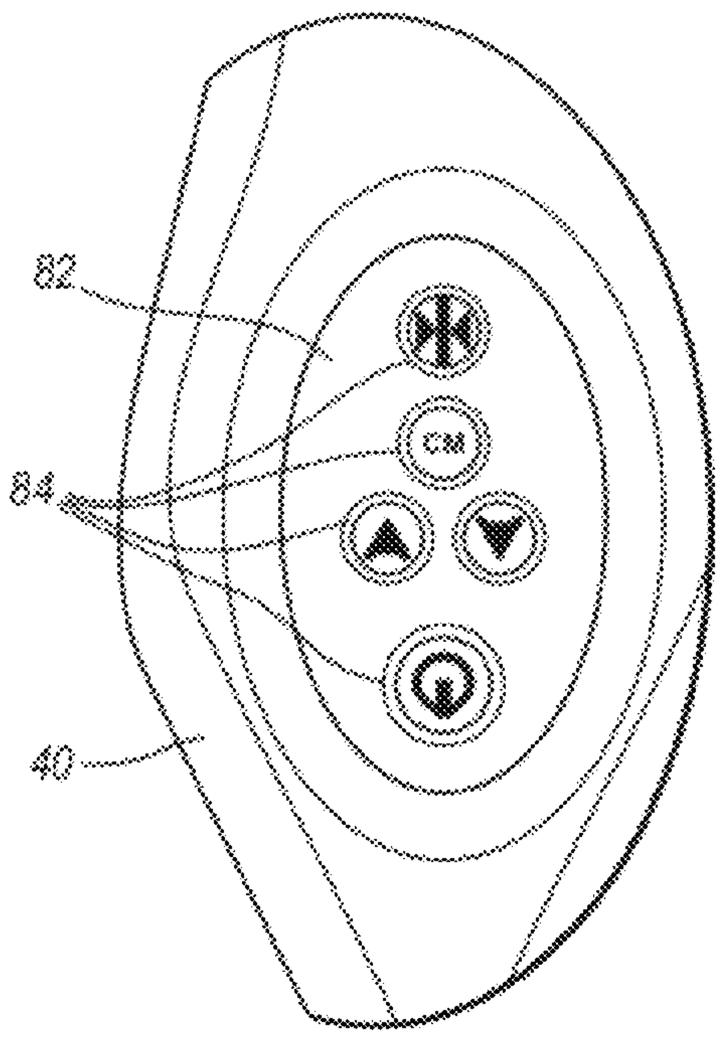

FIG. 3B

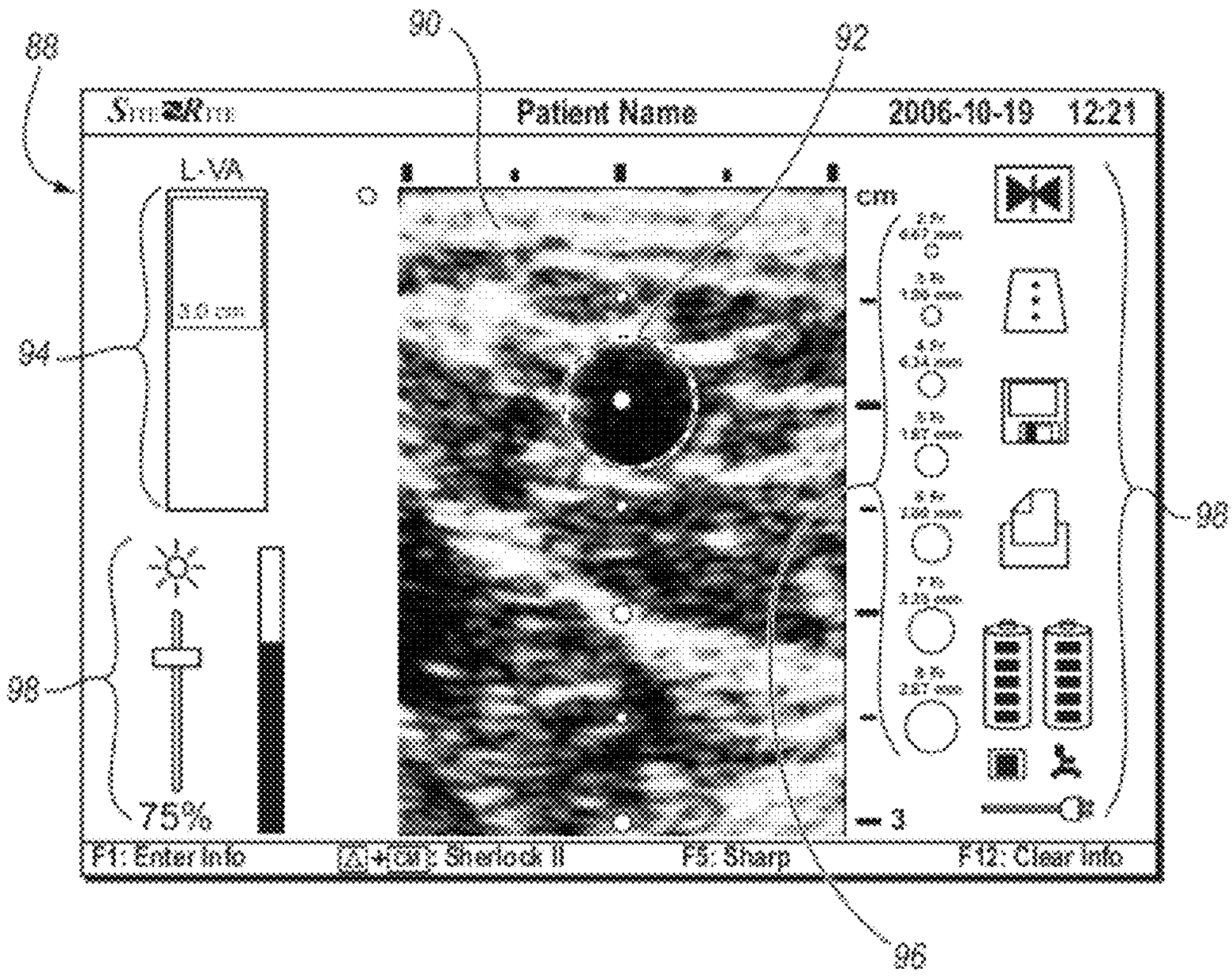
88
90
92
Patient Name
2006-10-19 12:21
L-VA
cm
94
98
75%
96
F1: Enter Info
F5: Sharp
F12: Clear Info

FIG. 4

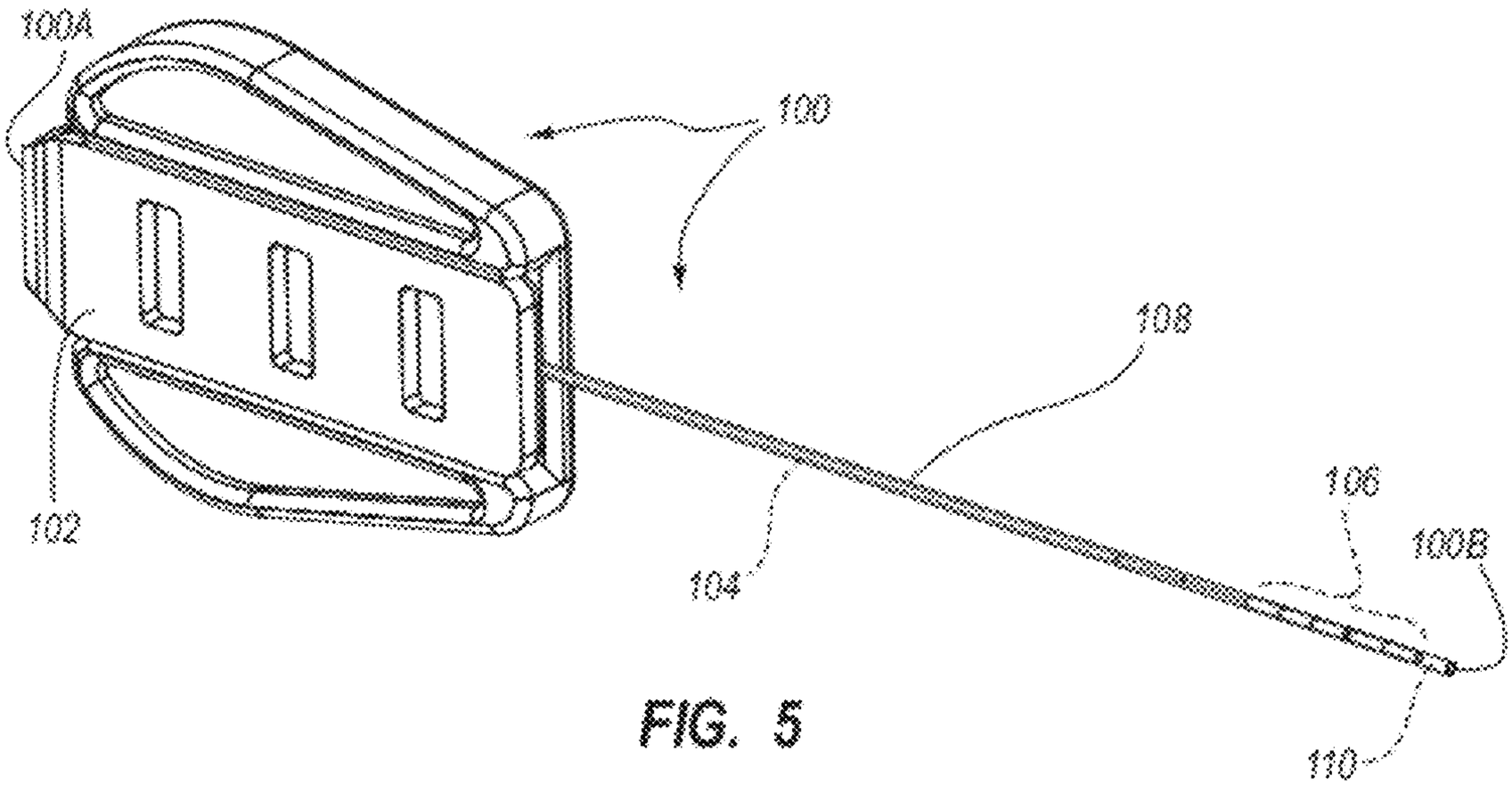
100A
100
102
104
106
108
100B
110

FIG. 5

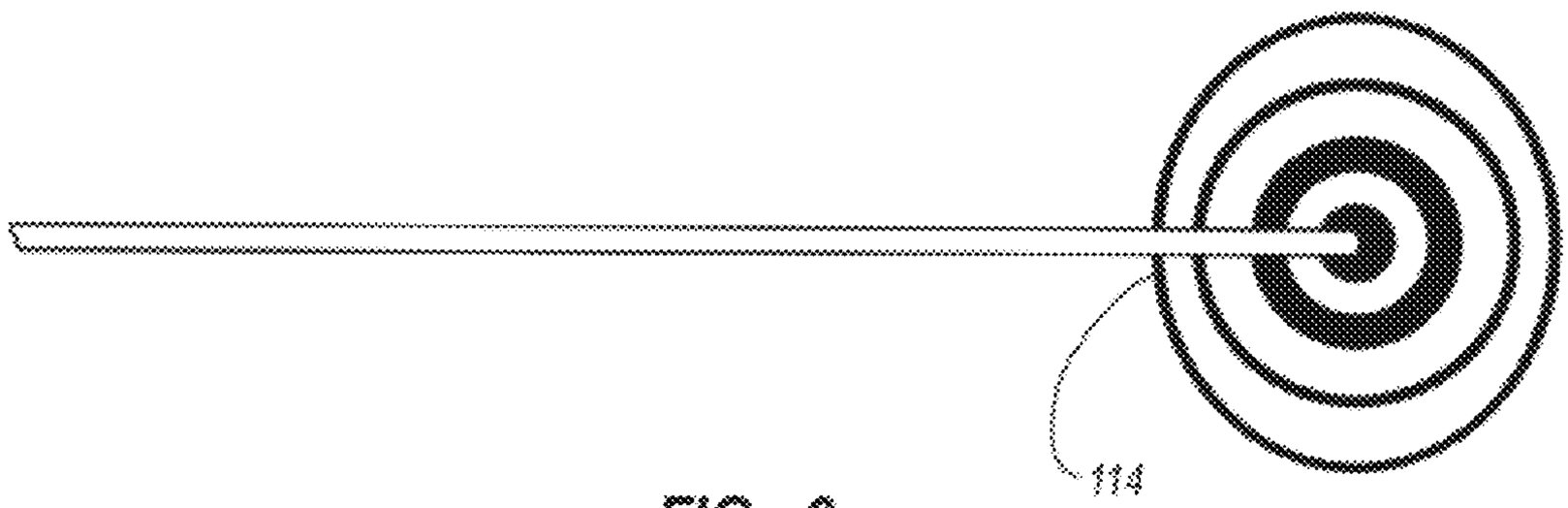

FIG. 6

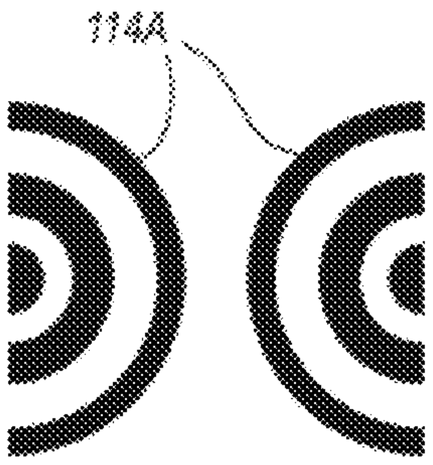

FIG. 7A

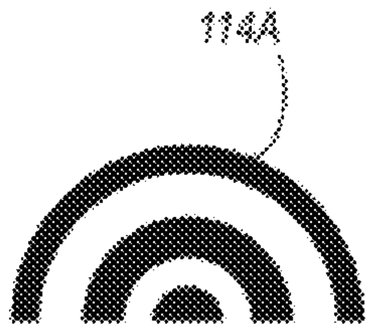

FIG. 7B

FIG. 7C

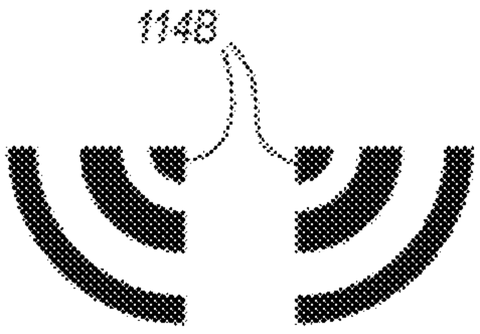

FIG. 7D

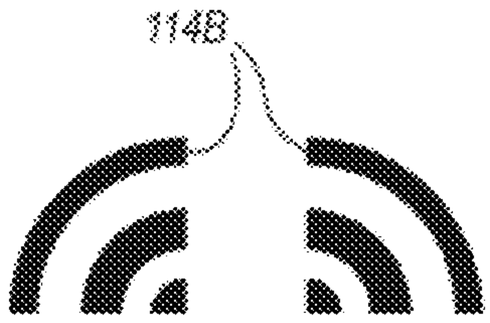

FIG. 7E

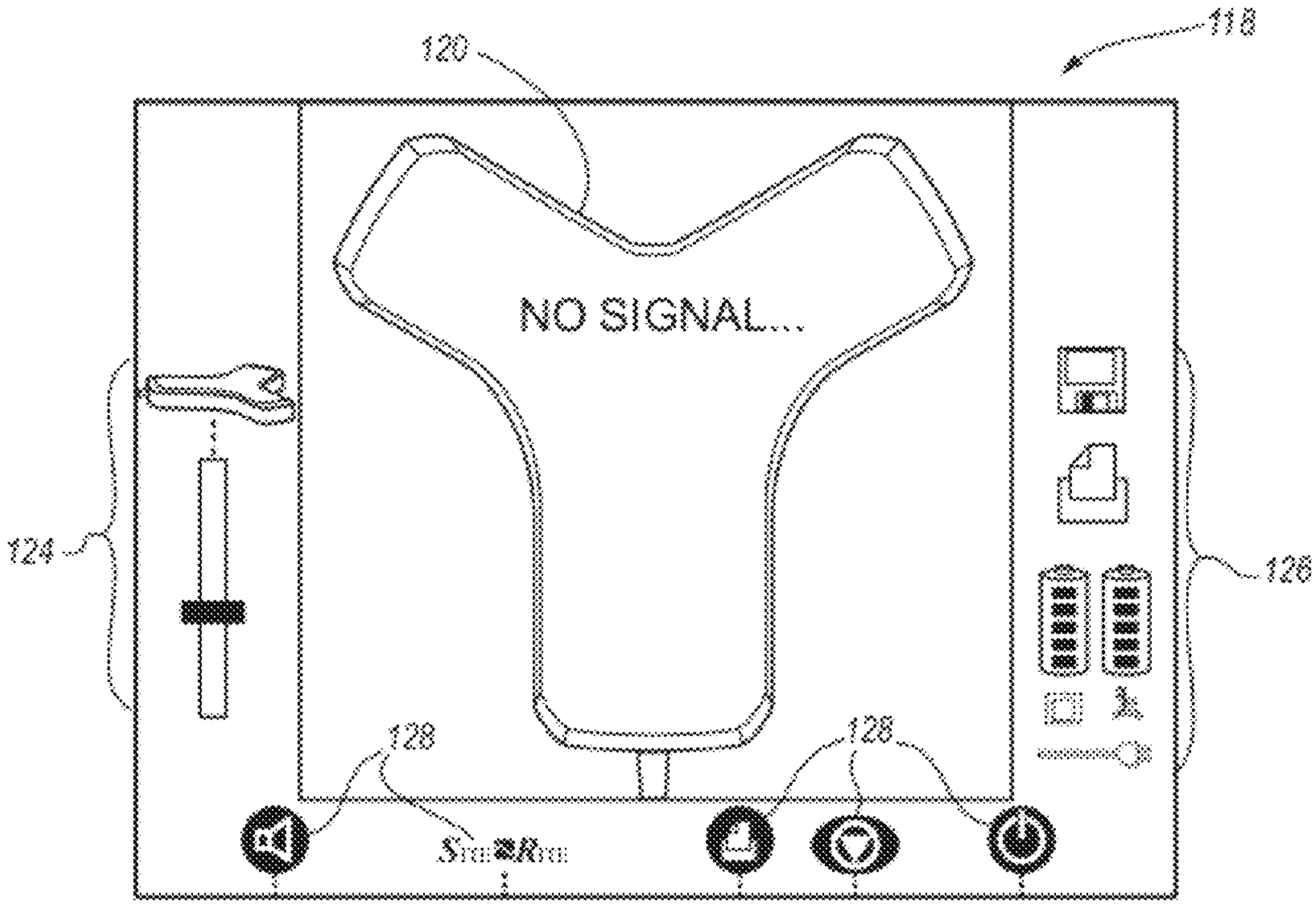
118
120
NO SIGNAL...
124
126
128
128
SELECT

FIG. 8A

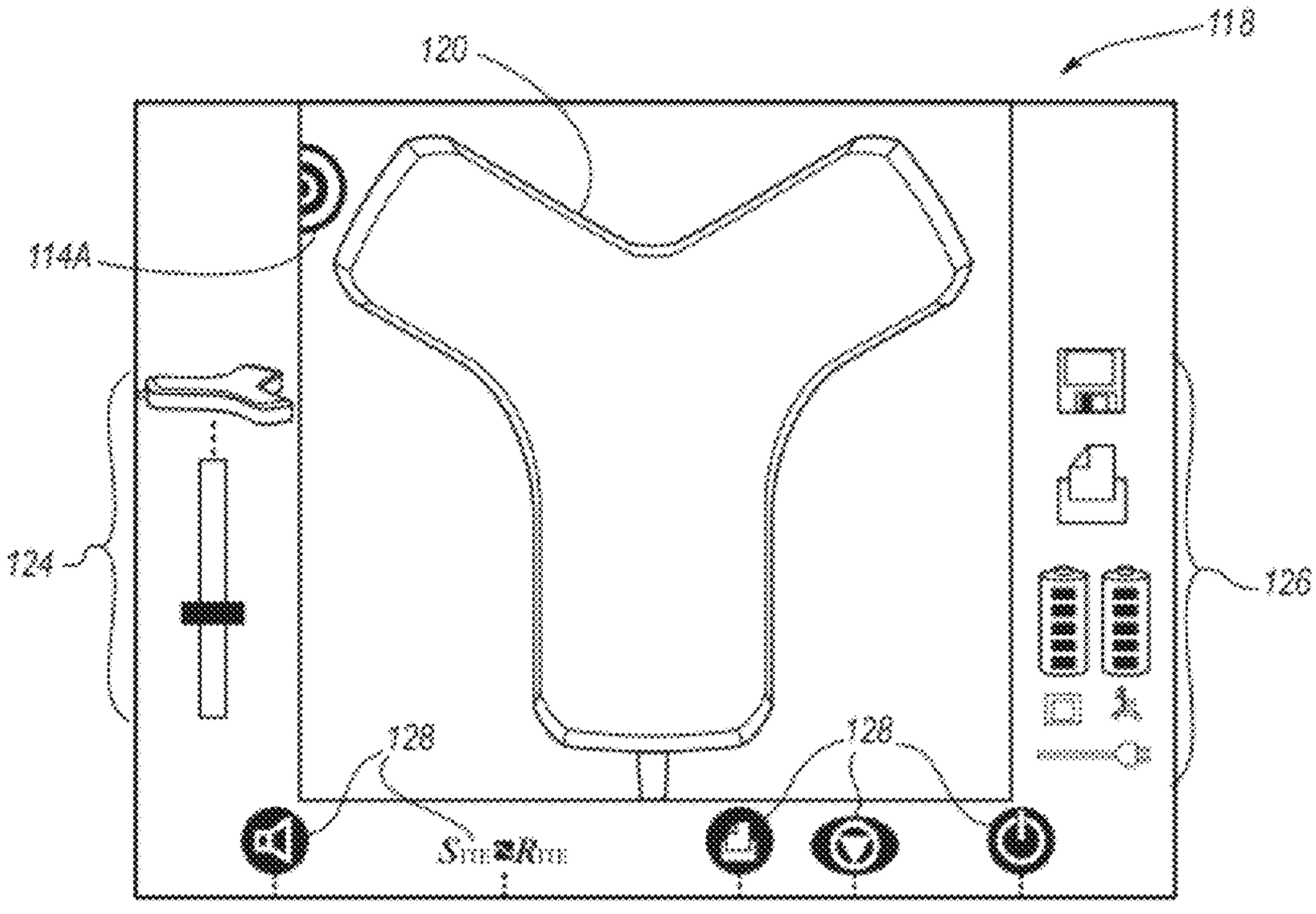
118
120
114A
124
126
128
128
SELECT

FIG. 8B

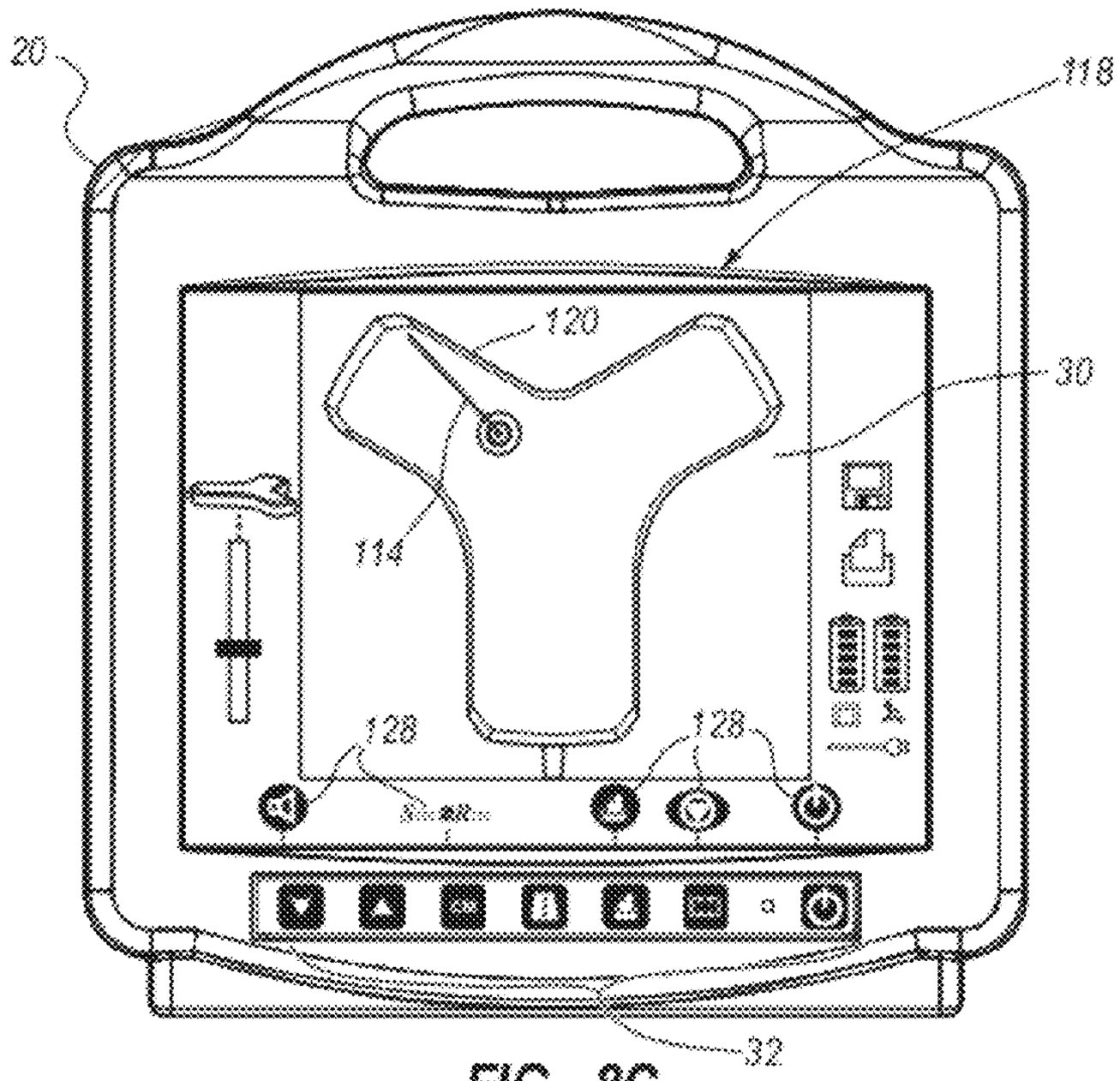
20
118
120
30
114
128
128
32

FIG. 8C

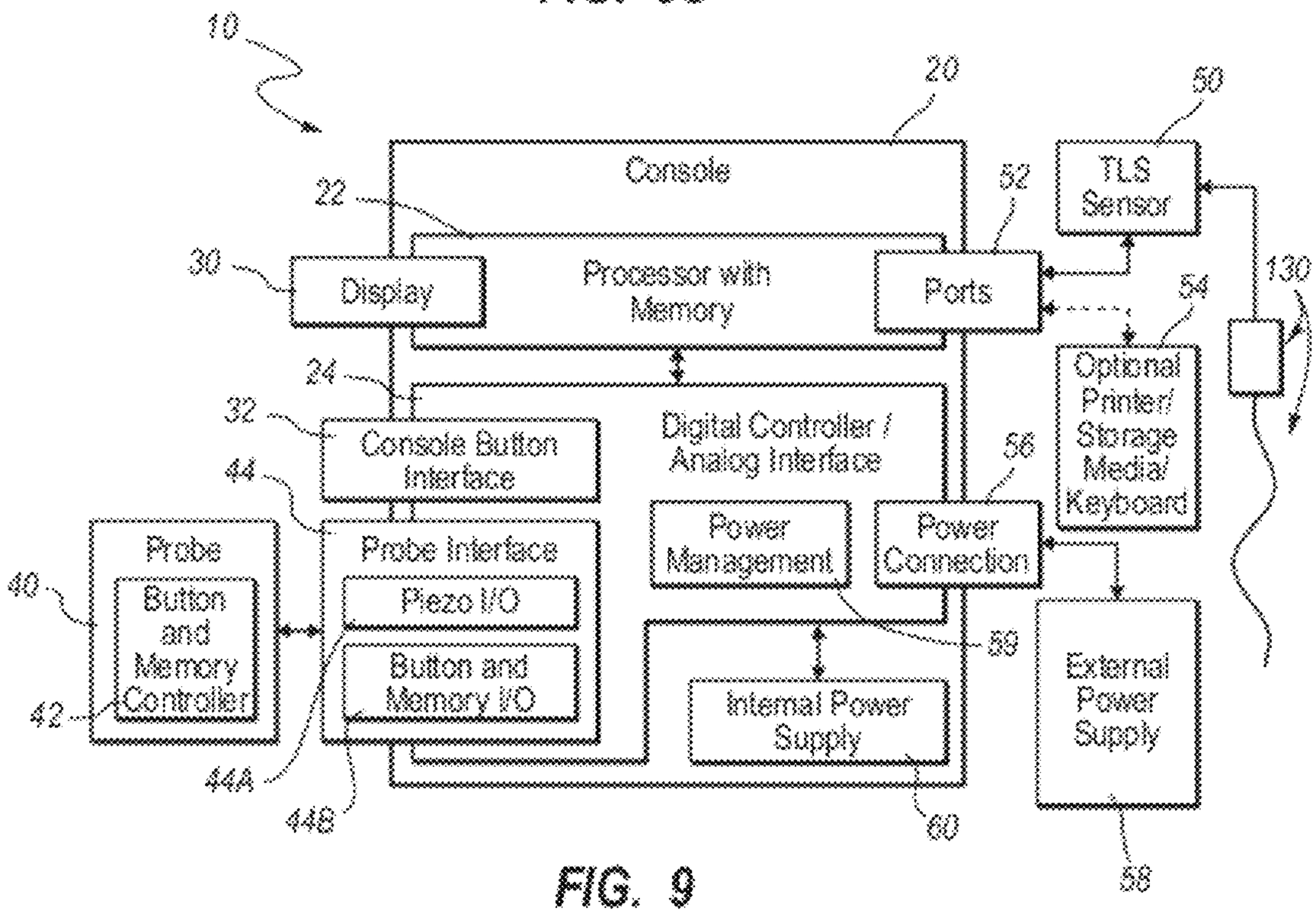
10
20
Console
22
50
TLS Sensor
52
30
Display
Processor with Memory
Ports
54
130
24
Optional Printer/ Storage Media/ Keyboard
32
Console Button Interface
Digital Controller / Analog Interface
56
44
Power Management
Power Connection
Probe
Probe Interface
40
Button and Memory Controller
Piezo I/O
59
Button and Memory I/O
External Power Supply
42
Internal Power Supply
44A
44B
60
58

FIG. 9

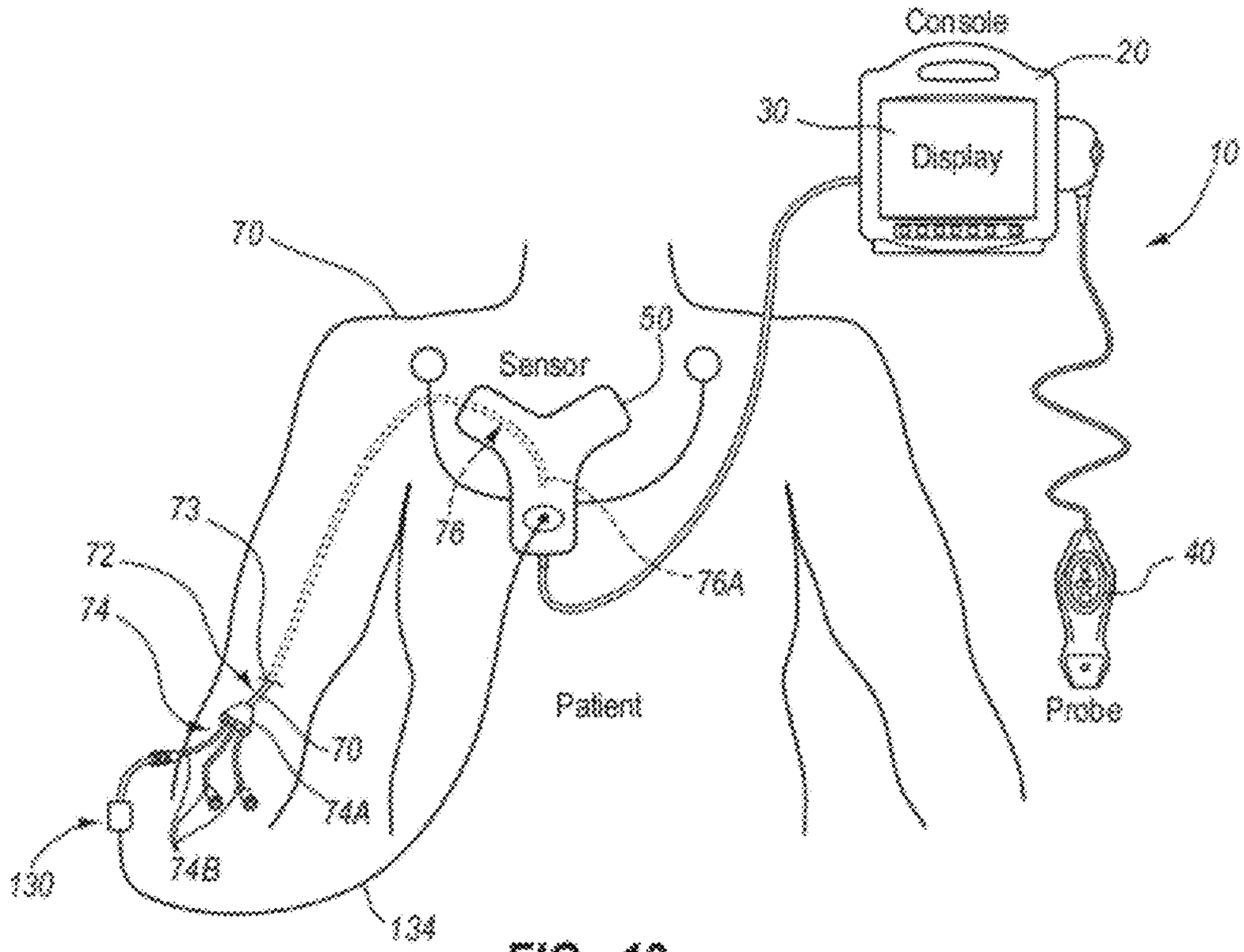
Console
20
30
Display
10
70
50
Sensor
73
72
74
76
76A
40
Patient
Probe
70
74A
74B
130
134

FIG. 10

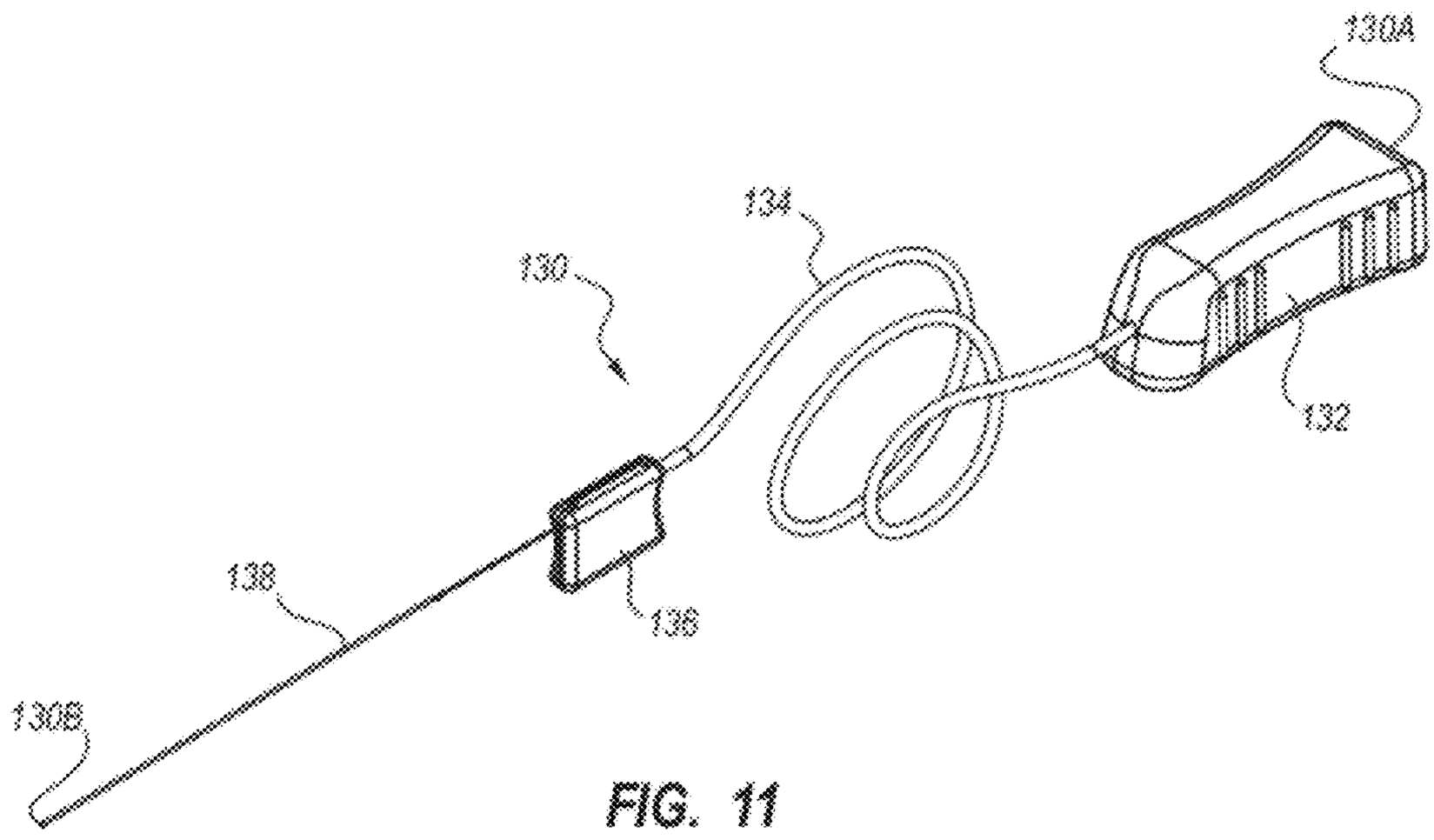
130A
134
130
132
138
138
130B

FIG. 11

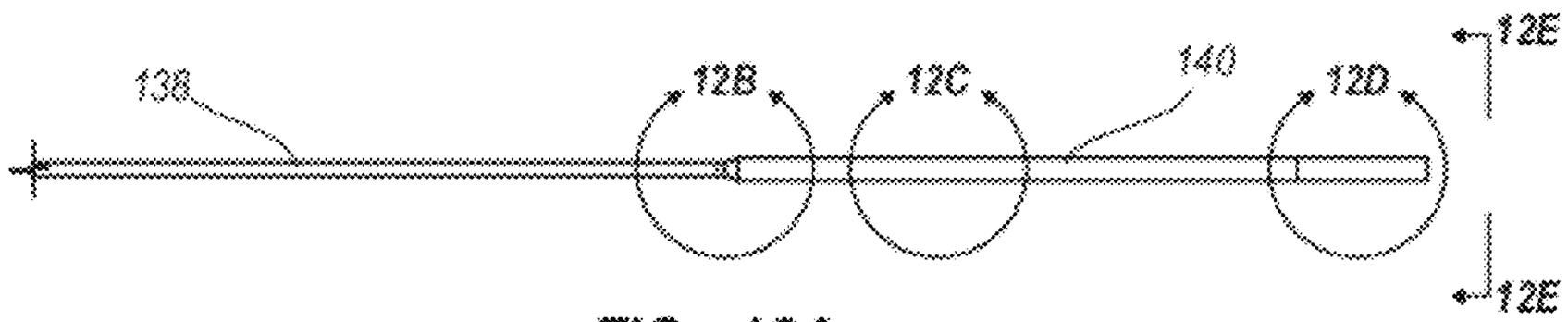

FIG. 12A

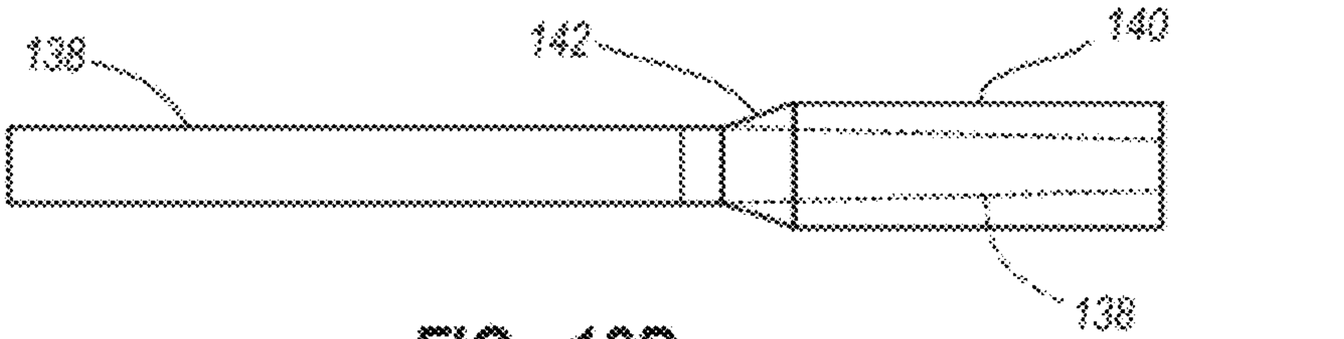

FIG. 12B

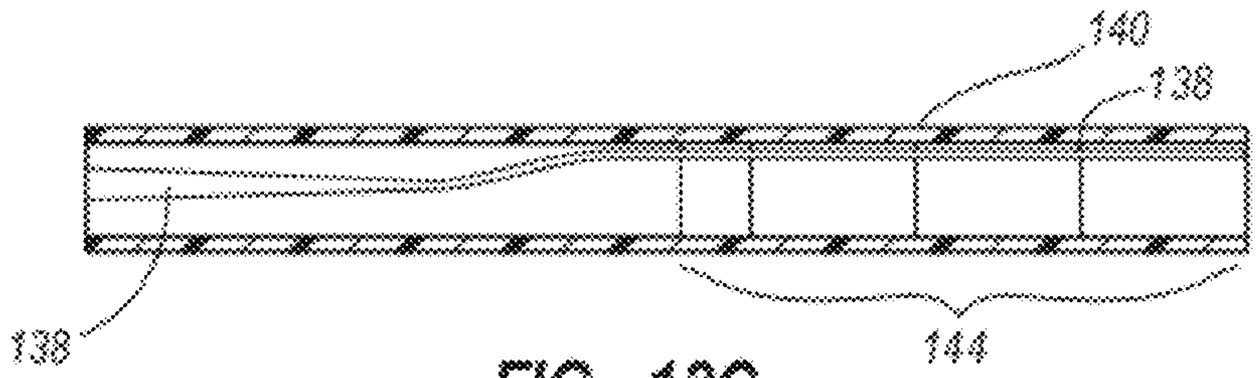

FIG. 12C

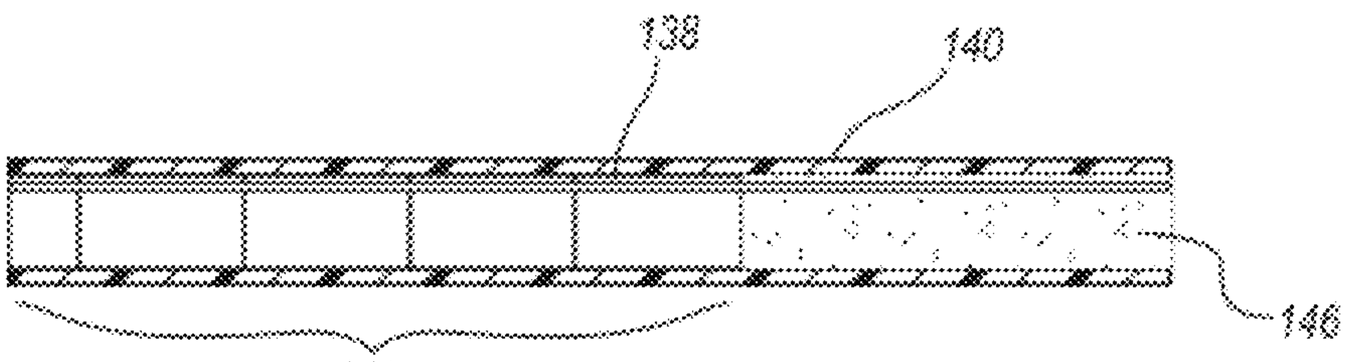

FIG. 12D

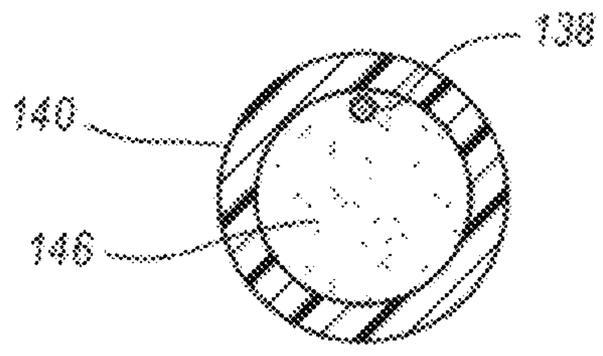

FIG. 12E

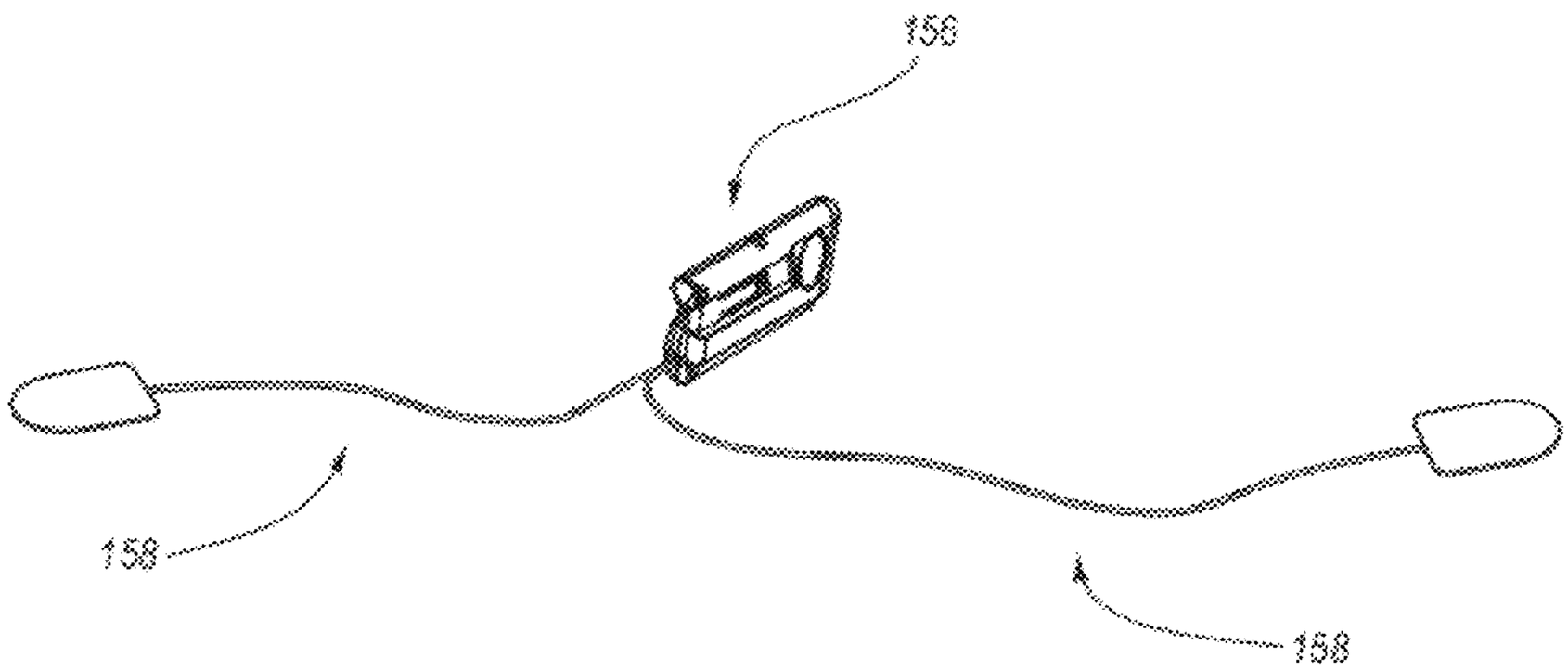

FIG. 13A

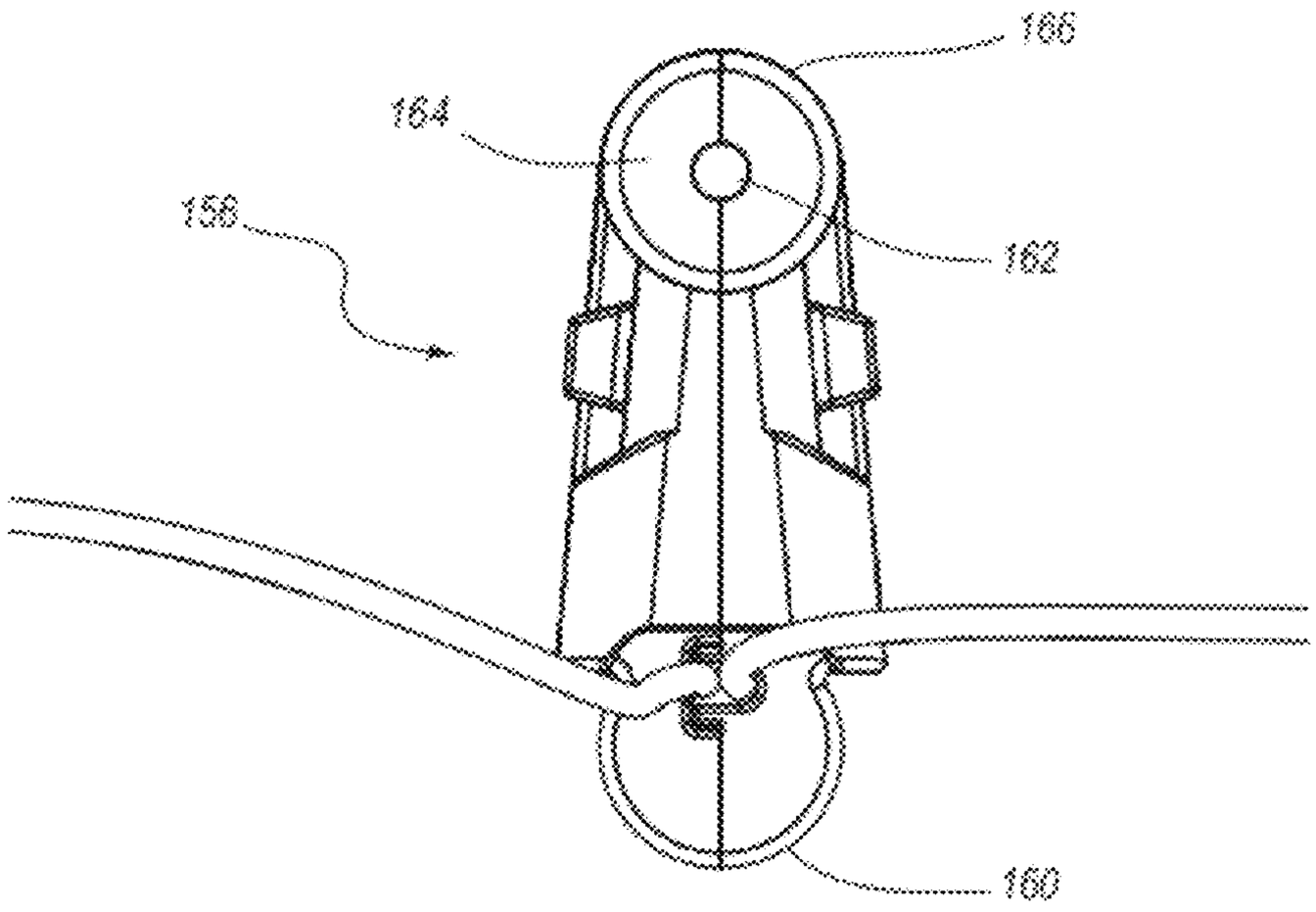

FIG. 13B

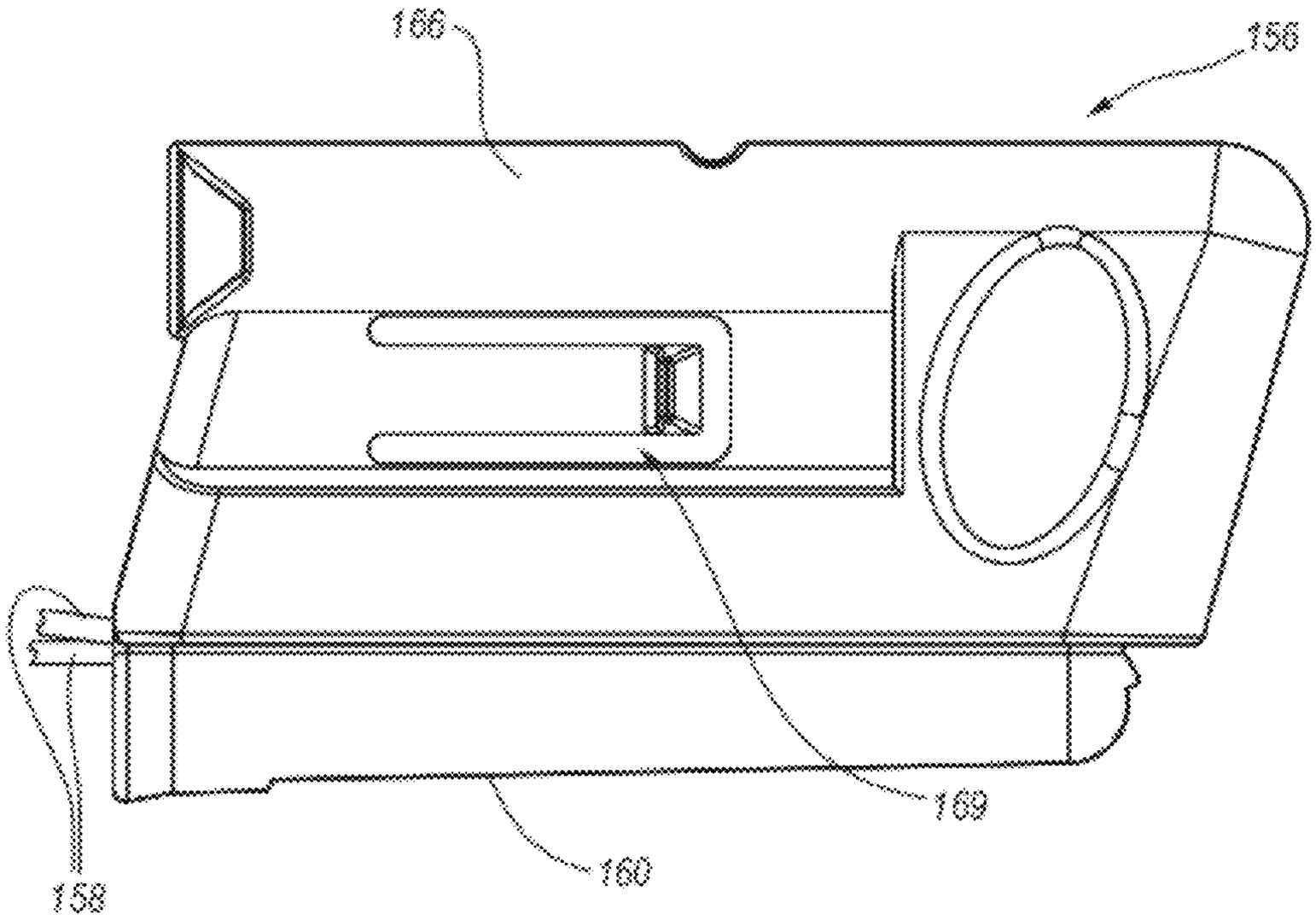

FIG. 13C

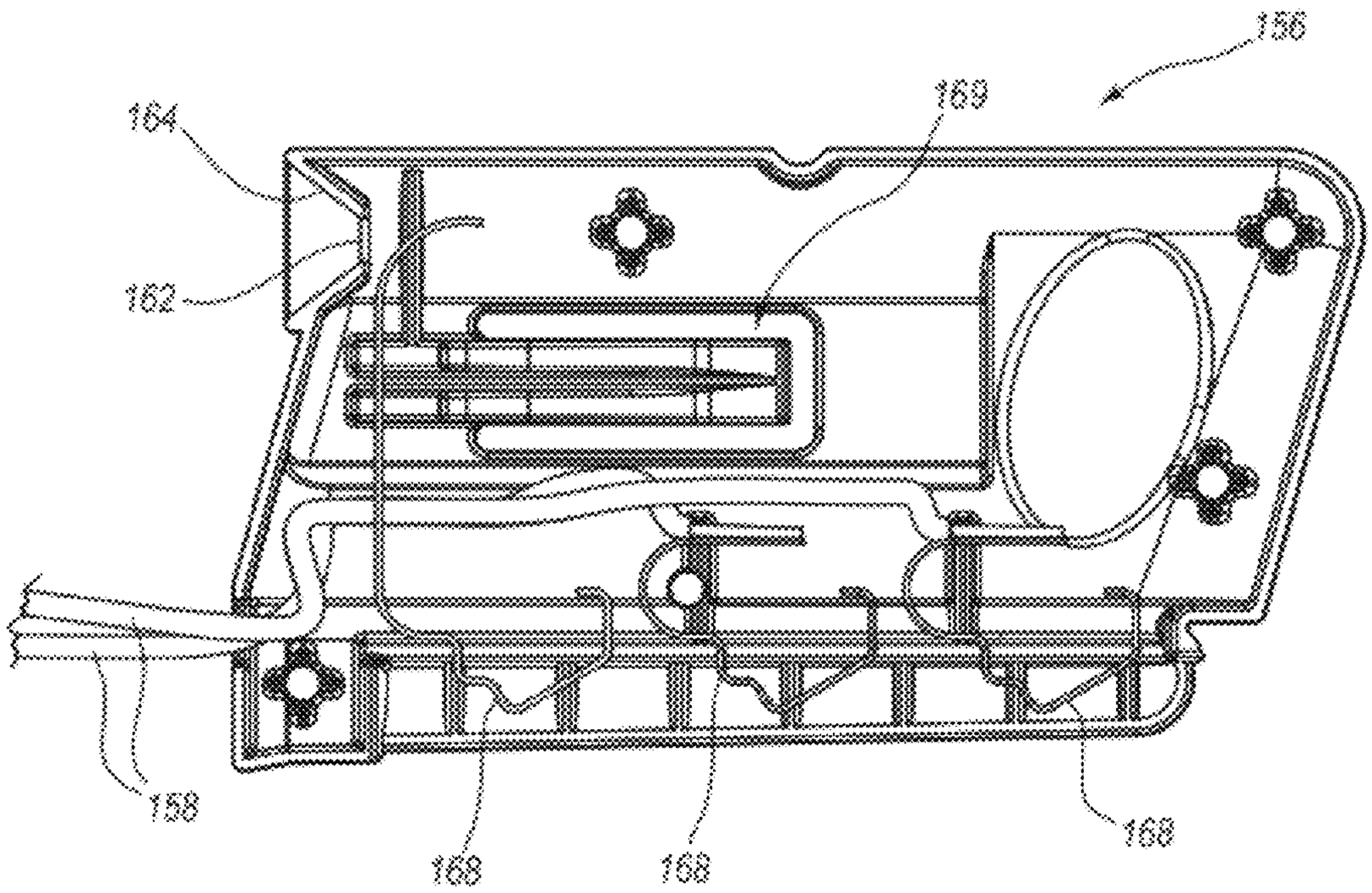

FIG. 13D

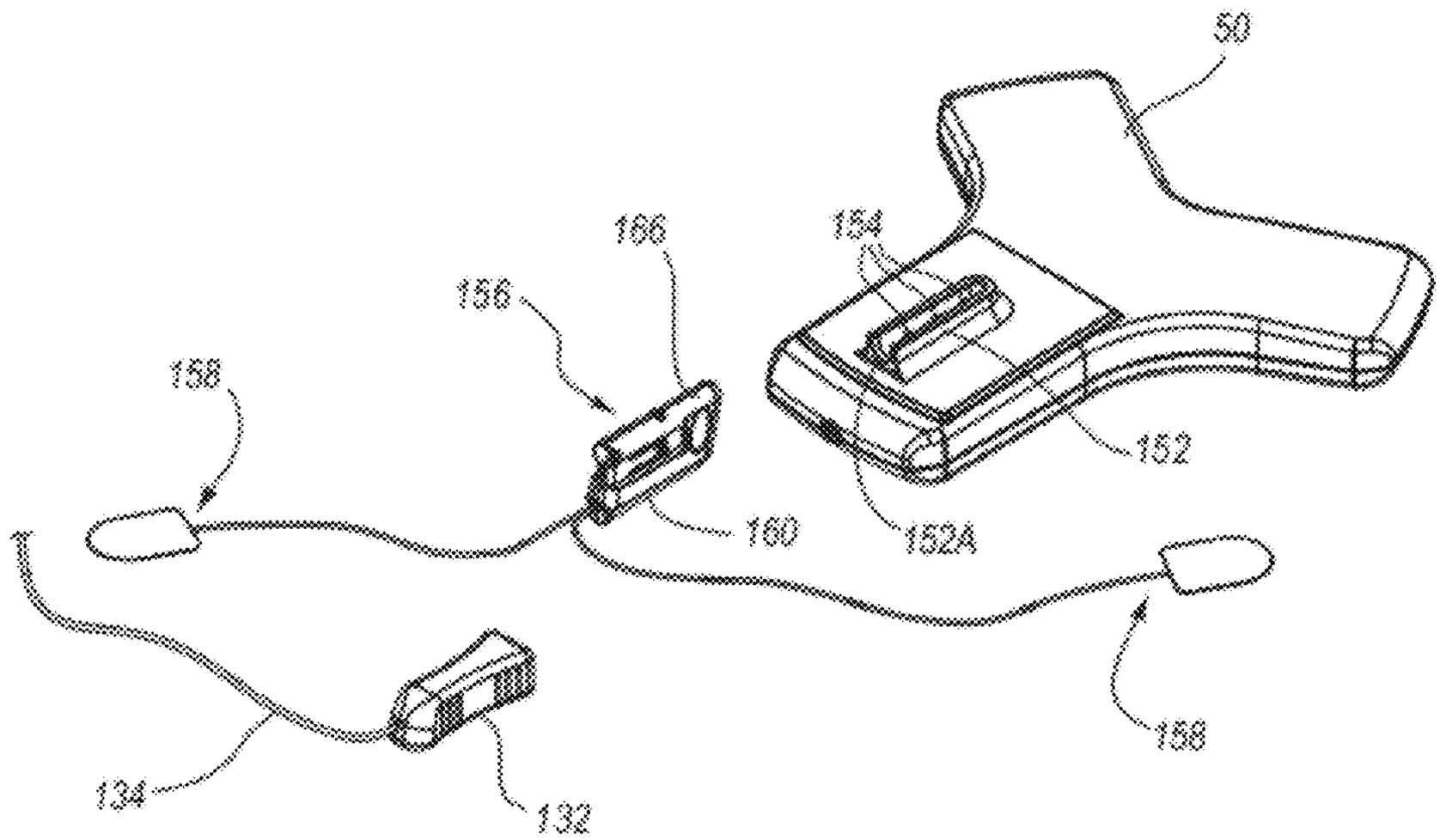

FIG. 14A

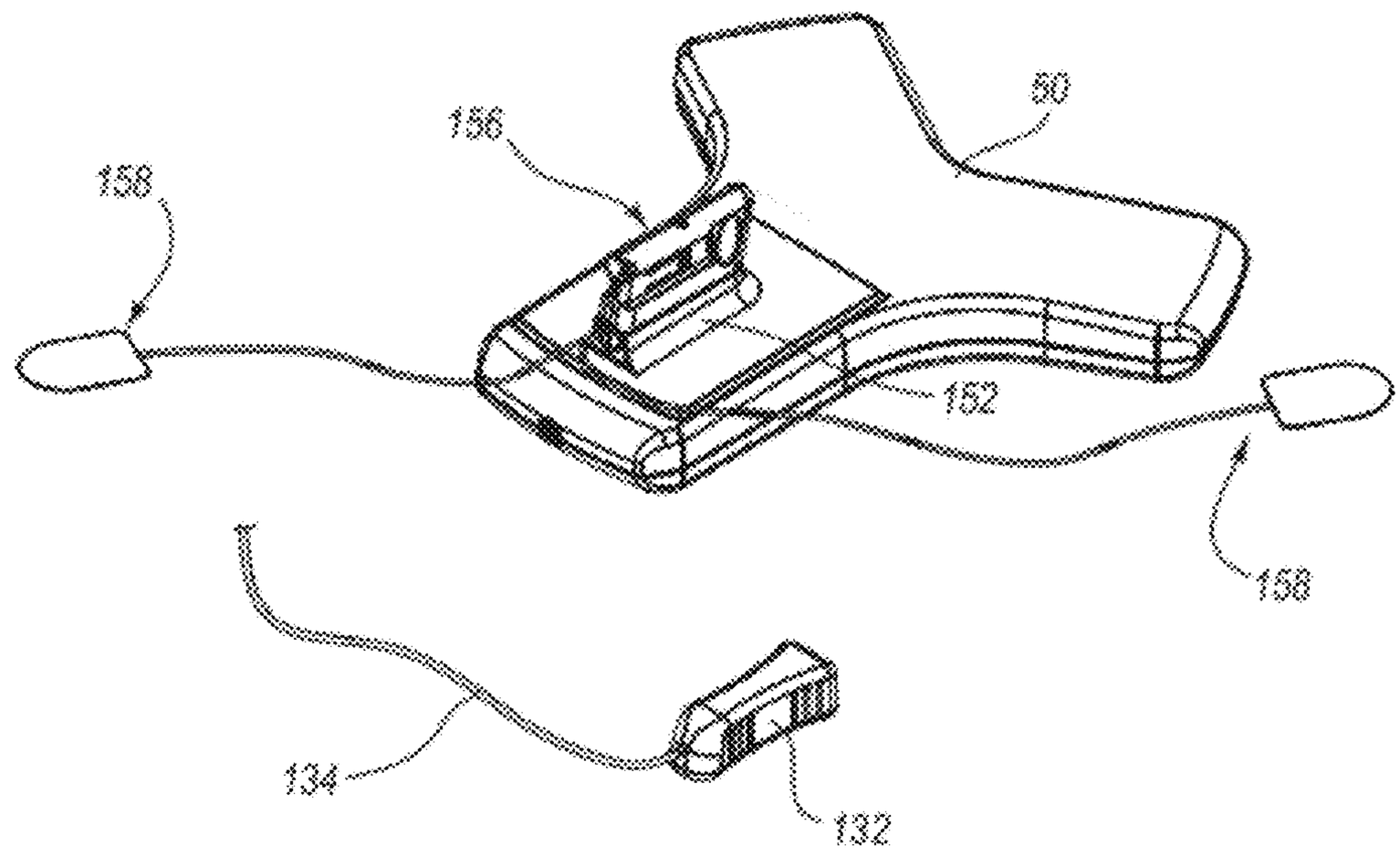

FIG. 14B

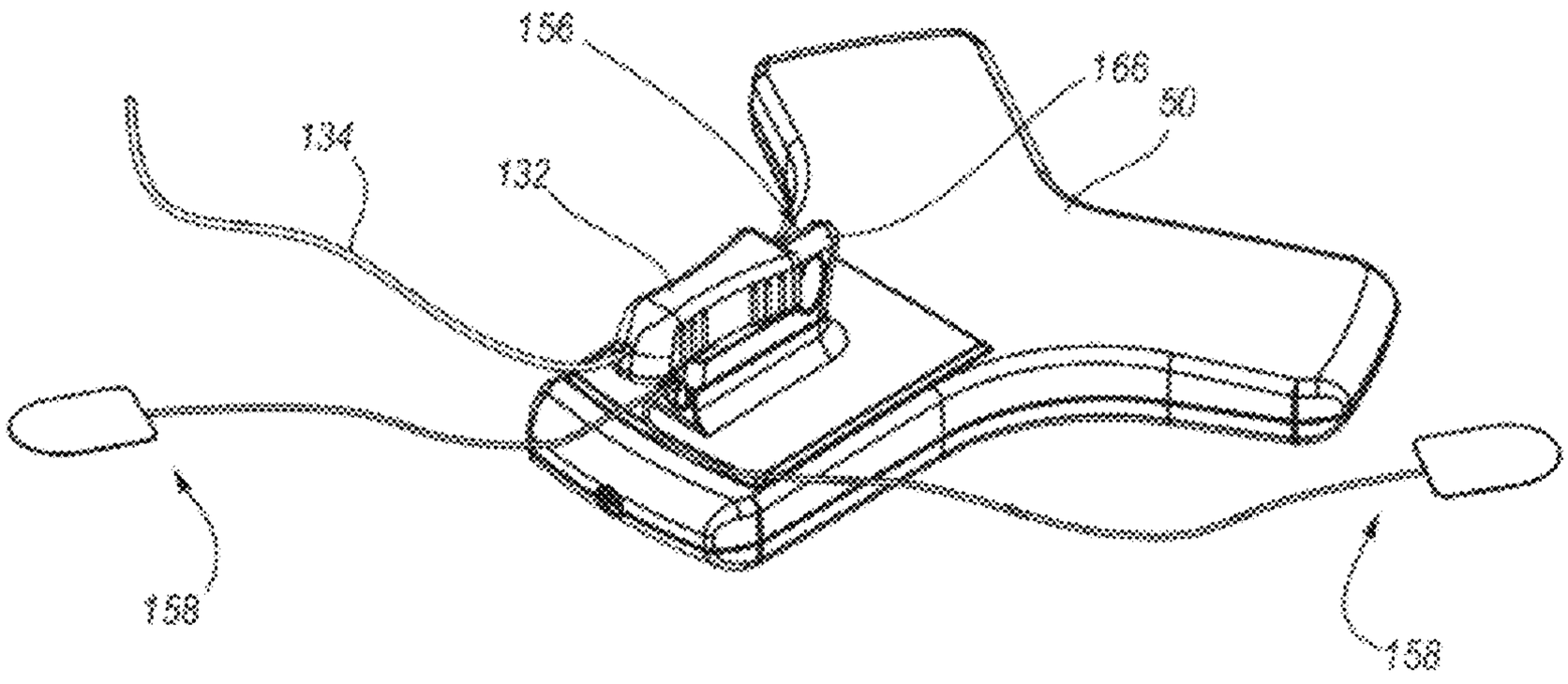

FIG. 14C

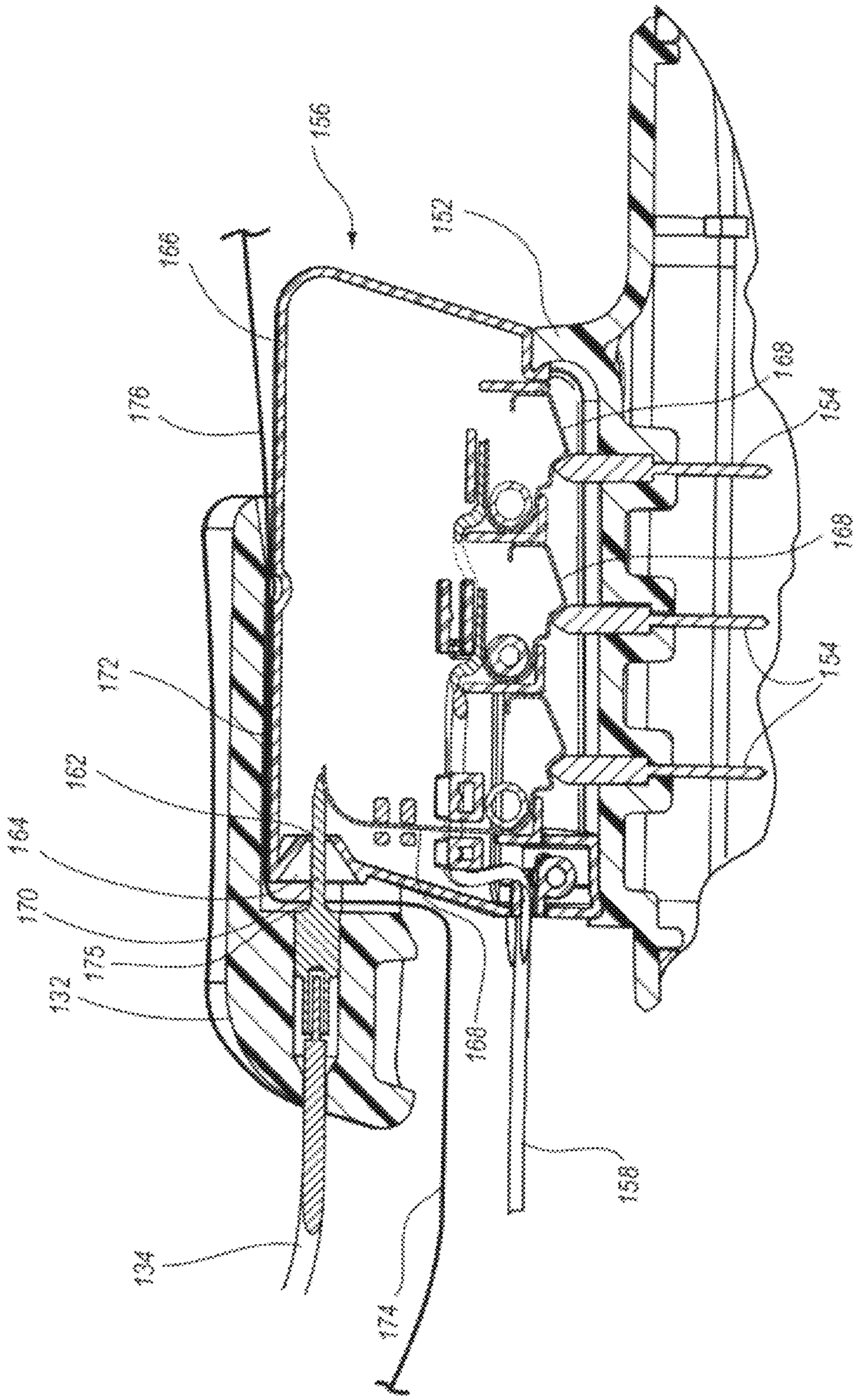
156
152
166
178
168
154
168
154
172
162
164
170
175
132
160
174
158
104

FIG. 15

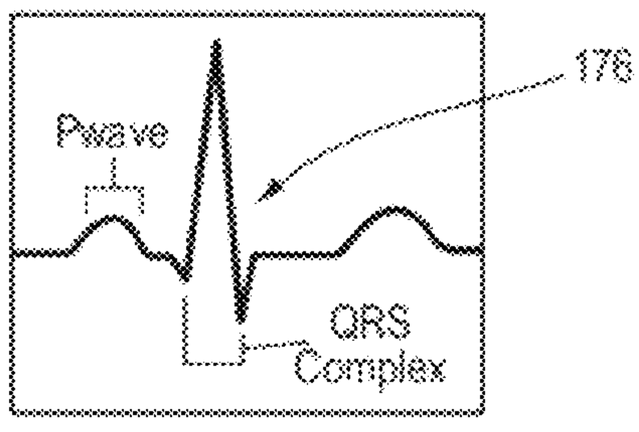
176
Pwave
QRS
Complex

FIG. 16

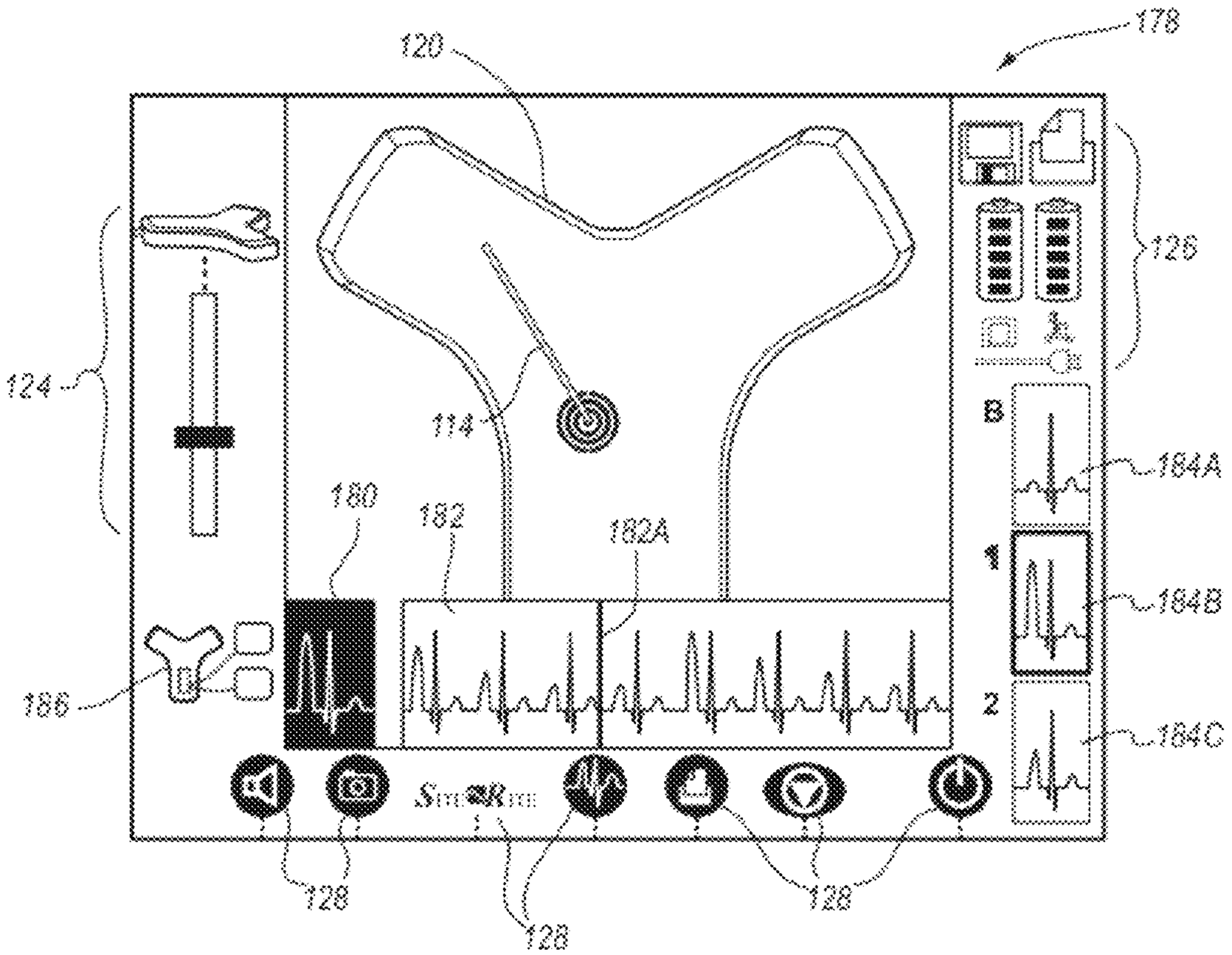
178
120
126
124
114
180
182
182A
B
184A
1
184B
186
2
184C
128
128
128

FIG. 17

INTEGRATED SYSTEM FOR INTRAVASCULAR PLACEMENT OF A CATHETER

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a division of U.S. patent application Ser. No. 12/323,273, now U.S. Pat. No. 8,388,541, filed Nov. 25, 2008, which claims the benefit of the following: 1) U.S. Provisional Application No. 60/990,242, filed Nov. 26, 2007; 2) U.S. Provisional Application No. 61/045,944, filed Apr. 17, 2008; 3) U.S. Provisional Application No. 61/091,233, filed Aug. 22, 2008; 4) U.S. Provisional Application No. 61/095,451, filed Sep. 9, 2008; and 5) U.S. Provisional Application No. 61/095,921, filed Sep. 10, 2008, each of which is incorporated by reference in its entirety into this application.

BRIEF SUMMARY

Briefly summarized, embodiments of the present invention are directed to an integrated catheter placement system configured for accurately placing a catheter within the vasculature of a patient. The integrated system employs at least two modalities for improving catheter placement accuracy: 1) ultrasound-assisted guidance for introducing the catheter into the patient's vasculature; and 2) a tip location system ("TLS"), or magnetically-based (e.g., via permanent magnet(s) or electromagnet(s)) tracking of the catheter tip during its advancement through the vasculature to detect and facilitate correction of any tip malposition during such advancement.

In one embodiment, the integrated system comprises a system console including a control processor, a tip location sensor for temporary placement on a portion of a body of the patient, and an ultrasound probe. The tip location sensor senses a magnetic field of a stylet disposed in a lumen of the catheter when the catheter is disposed in the vasculature. The ultrasound probe ultrasonically images a portion of the vasculature prior to introduction of the catheter into the vasculature. In addition, the ultrasound probe includes user input controls for controlling use of the ultrasound probe in an ultrasound mode and use of the tip location sensor in a tip location mode.

In another embodiment, a third modality, i.e., ECG signal-based catheter tip guidance, is included in the system to enable guidance of the catheter tip to a desired position with respect to a node of the patient's heart from which the ECG signals originate.

These and other features of embodiments of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of embodiments of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

A more particular description of the present disclosure will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. Example embodiments of the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

FIG. **1** is a block diagram depicting various elements of an integrated system for intravascular placement of a catheter, according to one example embodiment of the present invention;

FIG. **2** is a simplified view of a patient and a catheter being inserted therein with assistance of the integrated system of FIG. **1**;

FIGS. **3**A and **3**B are views of a probe of the integrated system of FIG. **1**;

FIG. **4** is a screenshot of an ultrasound image as depicted on a display of the integrated system of FIG. **1**;

FIG. **5** is a perspective view of a stylet employed in connection with the system of FIG. **1** in placing a catheter within a patient vasculature;

FIG. **6** is an icon as depicted on a display of the integrated system of FIG. **1**, indicating a position of a distal end of the stylet of FIG. **5** during catheter tip placement procedures;

FIGS. **7**A-**7**E depict various example icons that can be depicted on the display of the integrated system of FIG. **1** during catheter tip placement procedures;

FIGS. **8**A-**8**C are screenshots of images depicted on a display of the integrated system of FIG. **1** during catheter tip placement procedures;

FIG. **9** is a block diagram depicting various elements of an integrated system for intravascular placement of a catheter, according to another example embodiment of the present invention;

FIG. **10** is a simplified view of a patient and a catheter being inserted therein with assistance of the integrated system of FIG. **9**;

FIG. **11** is a perspective view of a stylet employed in connection with the integrated system of FIG. **9** in placing a catheter within a patient vasculature;

FIGS. **12**A-**12**E are various views of portions of the stylet of FIG. **11**;

FIGS. **13**A-**13**D are various views of a fin connector assembly for use with the integrated system of FIG. **9**;

FIGS. **14**A-**14**C are views showing the connection of a stylet tether and fin connector to a sensor of the integrated system of FIG. **9**;

FIG. **15** is a cross sectional view of the connection of the stylet tether, fin connector, and sensor shown in FIG. **14**C;

FIG. **16** is simplified view of an ECG trace of a patient; and

FIG. **17** is a screenshot of an image depicted on a display of the integrated system of FIG. **9** during catheter tip placement procedures.

DETAILED DESCRIPTION OF SELECTED EMBODIMENTS

Reference will now be made to figures wherein like structures will be provided with like reference designations. It is understood that the drawings are diagrammatic and schematic representations of exemplary embodiments of the present invention, and are neither limiting nor necessarily drawn to scale.

FIGS. **1**-**17** depict various features of embodiments of the present invention, which is generally directed to a catheter placement system configured for accurately placing a catheter within the vasculature of a patient. In one embodiment, the catheter placement system employs at least two modalities for improving catheter placement accuracy: 1) ultrasound-assisted guidance for introducing the catheter into the patient's vasculature; and 2) a tip location/navigation system ("TLS"), or magnetically-based tracking of the catheter tip during its advancement through the tortuous vasculature

path to detect and facilitate correction of any tip malposition during such advancement. The ultrasound guidance and tip location features of the present system according to one embodiment are integrated into a single device for use by a clinician placing the catheter. Integration of these two modalities into a single device simplifies the catheter placement process and results in relatively faster catheter placements. For instance, the integrated catheter placement system enables ultrasound and TLS activities to be viewed from a single display of the integrated system. Also, controls located on an ultrasound probe of the integrated device, which probe is maintained within the sterile field of the patient during catheter placement, can be used to control functionality of the system, thus precluding the need for a clinician to reach out of the sterile field in order to control the system.

In another embodiment, a third modality, i.e., ECG signal-based catheter tip guidance, is included in the integrated system to enable guidance of the catheter tip to a desired position with respect to a node of the patient's heart from which the ECG signals originate. Such ECG-based positional assistance is also referred to herein as "tip confirmation."

Combination of the three modalities above according to one embodiment enables the catheter placement system to facilitate catheter placement within the patient's vasculature with a relatively high level of accuracy, i.e., placement of the distal tip of the catheter in a predetermined and desired position. Moreover, because of the ECG-based guidance of the catheter tip, correct tip placement may be confirmed without the need for a confirmatory X-ray. This, in turn, reduces the patient's exposure to potentially harmful x-rays, the cost and time involved in transporting the patient to and from the x-ray department, costly and inconvenient catheter repositioning procedures, etc.

Reference is first made to FIGS. **1** and **2** which depict various components of a catheter placement system ("system"), generally designated at **10**, configured in accordance with one example embodiment of the present invention. As shown, the system **10** generally includes a console **20**, display **30**, probe **40**, and sensor **50**, each of which is described in further detail below.

FIG. **2** shows the general relation of these components to a patient **70** during a procedure to place a catheter **72** into the patient vasculature through a skin insertion site **73**. FIG. **2** shows that the catheter **72** generally includes a proximal portion **74** that remains exterior to the patient and a distal potion **76** that resides within the patient vasculature after placement is complete. The system **10** is employed to ultimately position a distal tip **76**A of the catheter **72** in a desired position within the patient vasculature. In one embodiment, the desired position for the catheter distal tip **76**A is proximate the patient's heart, such as in the lower one-third ($\frac{1}{3}^{rd}$) portion of the Superior Vena Cava ("SVC"). Of course, the system **10** can be employed to place the catheter distal tip in other locations. The catheter proximal portion **74** further includes a hub **74**A that provides fluid communication between the one or more lumens of the catheter **72** and one or more extension legs **74**B extending proximally from the hub.

An example implementation of the console **20** is shown in FIG. **8**C, though it is appreciated that the console can take one of a variety of forms. A processor **22**, including non-volatile memory such as EEPROM for instance, is included in the console **20** for controlling system function during operation of the system **10**, thus acting as a control processor. A digital controller/analog interface **24** is also included with the console **20** and is in communication with both the processor **22** and other system components to govern interfacing between the probe **40**, sensor **50**, and other system components.

The system **10** further includes ports **52** for connection with the sensor **50** and optional components **54** including a printer, storage media, keyboard, etc. The ports in one embodiment are USB ports, though other port types or a combination of port types can be used for this and the other interfaces connections described herein. A power connection **56** is included with the console **20** to enable operable connection to an external power supply **58**. An internal battery **60** can also be employed, either with or exclusive of an external power supply. Power management circuitry **59** is included with the digital controller/analog interface **24** of the console to regulate power use and distribution.

The display **30** in the present embodiment is integrated into the console **20** and is used to display information to the clinician during the catheter placement procedure. In another embodiment, the display may be separate from the console. As will be seen, the content depicted by the display **30** changes according to which mode the catheter placement system is in: US, TLS, or in other embodiments, ECG tip confirmation. In one embodiment, a console button interface **32** (see FIGS. **1**, **8**C) and buttons included on the probe **40** can be used to immediately call up a desired mode to the display **30** by the clinician to assist in the placement procedure. In one embodiment, information from multiple modes, such as TLS and ECG, may be displayed simultaneously, such as in FIG. **17**. Thus, the single display **30** of the system console **20** can be employed for ultrasound guidance in accessing a patient's vasculature, TLS guidance during catheter advancement through the vasculature, and (as in later embodiments) ECG-based confirmation of catheter distal tip placement with respect to a node of the patient's heart. In one embodiment, the display **30** is an LCD device.

FIGS. **3**A and **3**B depict features of the probe **40** according to one embodiment. The probe **40** is employed in connection with the first modality mentioned above, i.e., ultrasound ("US")-based visualization of a vessel, such as a vein, in preparation for insertion of the catheter **72** into the vasculature. Such visualization gives real time ultrasound guidance for introducing the catheter into the vasculature of the patient and assists in reducing complications typically associated with such introduction, including inadvertent arterial puncture, hematoma, pneumothorax, etc.

The handheld probe **40** includes a head **80** that houses a piezoelectric array for producing ultrasonic pulses and for receiving echoes thereof after reflection by the patient's body when the head is placed against the patient's skin proximate the prospective insertion site **73** (FIG. **2**). The probe **40** further includes a plurality of control buttons **84**, which can be included on a button pad **82**. In the present embodiment, the modality of the system **10** can be controlled by the control buttons **84**, thus eliminating the need for the clinician to reach out of the sterile field, which is established about the patient insertion site prior to catheter placement, to change modes via use of the console button interface **32**.

As such, in one embodiment a clinician employs the first (US) modality to determine a suitable insertion site and establish vascular access, such as with a needle or introducer, then with the catheter. The clinician can then seamlessly switch, via button pushes on the probe button pad **82**, to the second (TLS) modality without having to reach out of the sterile field. The TLS mode can then be used to assist in

advancement of the catheter **72** through the vasculature toward an intended destination.

FIG. **1** shows that the probe **40** further includes button and memory controller **42** for governing button and probe operation. The button and memory controller **42** can include non-volatile memory, such as EEPROM, in one embodiment. The button and memory controller **42** is in operable communication with a probe interface **44** of the console **20**, which includes a piezo input/output component **44**A for interfacing with the probe piezoelectric array and a button and memory input/output component **44**B for interfacing with the button and memory controller **42**.

FIG. **4** shows an example screenshot **88** as depicted on the display **30** while the system **10** is in its first ultrasound modality. An image **90** of a subcutaneous region of the patient **70** is shown, depicting a cross section of a vein **92**. The image **90** is produced by operation of the piezoelectric array of the probe **40**. also included on the display screenshot **88** is a depth scale indicator **94**, providing information regarding the depth of the image **90** below the patient's skin, a lumen size scale **96** that provides information as to the size of the vein **92** relative to standard catheter lumen sizes, and other indicia **98** that provide information regarding status of the system **10** or possible actions to be taken, e.g., freeze frame, image templates, data save, image print, power status, image brightness, etc.

Note that while a vein is depicted in the image **90**, other body lumens or portions can be imaged in other embodiments. Note that the US mode shown in FIG. **4** can be simultaneously depicted on the display **30** with other modes, such as the TLS mode, if desired. In addition to the visual display **30**, aural information, such as beeps, tones, etc., can also be employed by the system **10** to assist the clinician during catheter placement. Moreover, the buttons included on the probe **40** and the console button interface **32** can be configured in a variety of ways, including the use of user input controls in addition to buttons, such as slide switches, toggle switches, electronic or touch-sensitive pads, etc. Additionally, both US and TLS activities can occur simultaneously or exclusively during use of the system **10**.

As just described, the handheld ultrasound probe **40** is employed as part of the integrated catheter placement system **10** to enable US visualization of the peripheral vasculature of a patient in preparation for transcutaneous introduction of the catheter. In the present example embodiment, however, the probe is also employed to control functionality of the TLS portion, or second modality, of the system **10** when navigating the catheter toward its desired destination within the vasculature as described below. Again, as the probe **40** is used within the sterile field of the patient, this feature enables TLS functionality to be controlled entirely from within the sterile field. Thus the probe **40** is a dual-purpose device, enabling convenient control of both US and TLS functionality of the system **10** from the sterile field. In one embodiment, the probe can also be employed to control some or all ECG-related functionality, or third modality, of the catheter placement system **10**, as described further below.

The catheter placement system **10** further includes the second modality mentioned above, i.e., the magnetically-based catheter TLS, or tip location system. The TLS enables the clinician to quickly locate and confirm the position and/or orientation of the catheter **72**, such as a peripherally-inserted central catheter ("PICC"), central venous catheter ("CVC"), or other suitable catheter, during initial placement into and advancement through the vasculature of the patient **70**. Specifically, the TLS modality detects a magnetic field generated by a magnetic element-equipped tip location stylet, which is pre-loaded in one embodiment into a longitudinally defined lumen of the catheter **72**, thus enabling the clinician to ascertain the general location and orientation of the catheter tip within the patient body. In one embodiment, the magnetic assembly can be tracked using the teachings of one or more of the following U.S. Pat. Nos. 5,775,322; 5,879,297; 6,129,668; 6,216,028; and 6,263,230. The contents of the afore-mentioned U.S. patents are incorporated herein by reference in their entireties. The TLS also displays the direction in which the catheter tip is pointing, thus further assisting accurate catheter placement. The TLS further assists the clinician in determining when a malposition of the catheter tip has occurred, such as in the case where the tip has deviated from a desired venous path into another vein.

As mentioned, the TLS utilizes a stylet to enable the distal end of the catheter **72** to be tracked during its advancement through the vasculature. FIG. **5** gives an example of such a stylet **100**, which includes a proximal end **100**A and a distal end **100**B. A handle **102** is included at the stylet proximal end **100**A, with a core wire **104** extending distally therefrom. A magnetic assembly is disposed distally of the core wire **104**. The magnetic assembly includes one or more magnetic elements **106** disposed adjacent one another proximate the stylet distal end **100**B and encapsulated by tubing **108**. In the present embodiment, a plurality of magnetic elements **106** is included, each element including a solid, cylindrically shaped ferromagnetic stacked end-to-end with the other magnetic elements. An adhesive tip **110** can fill the distal tip of the tubing **108**, distally to the magnetic elements **106**.

Note that in other embodiments, the magnetic elements may vary from the design in not only shape, but also composition, number, size, magnetic type, and position in the stylet distal segment. For example, in one embodiment, the plurality of ferromagnetic magnetic elements is replaced with an electromagnetic assembly, such as an electromagnetic coil, which produces a magnetic field for detection by the sensor. Another example of an assembly usable here can be found in U.S. Pat. No. 5,099,845 entitled "Medical Instrument Location Means," which is incorporated herein by reference in its entirety. Yet other examples of stylets including magnetic elements that can be employed with the TLS modality can be found in U.S. Pat. No. 8,784,336 entitled "Stylet Apparatuses and Methods of Manufacture," which is incorporated herein by reference in its entirety. These and other variations are therefore contemplated by embodiments of the present invention. It should appreciated herein that "stylet" as used herein can include any one of a variety of devices configured for removable placement within a lumen of the catheter to assist in placing a distal end of the catheter in a desired location within the patient's vasculature.

FIG. **2** shows disposal of the stylet **100** substantially within a lumen in the catheter **72** such that the proximal portion thereof extends proximally from the catheter lumen, through the hub **74**A and out through a selected one of the extension legs **74**B. So disposed within a lumen of the catheter, the distal end **100**B of the stylet **100** is substantially co-terminal with the distal catheter end **76**A such that detection by the TLS of the stylet distal end correspondingly indicates the location of the catheter distal end.

The TLS sensor **50** is employed by the system **10** during TLS operation to detect a magnetic field produced by the magnetic elements **106** of the stylet **100**. As seen in FIG. **2**, the TLS sensor **50** is placed on the chest of the patient during

catheter insertion. The TLS sensor **50** is placed on the chest of the patient in a predetermined location, such as through the use of external body landmarks, to enable the magnetic field of the stylet magnetic elements **106**, disposed in the catheter **72** as described above, to be detected during catheter transit through the patient vasculature. Again, as the magnetic elements **106** of the stylet magnetic assembly are co-terminal with the distal end **76**A of the catheter **72** (FIG. **2**), detection by the TLS sensor **50** of the magnetic field of the magnetic elements provides information to the clinician as to the position and orientation of the catheter distal end during its transit.

In greater detail, the TLS sensor **50** is operably connected to the console **20** of the system **10** via one or more of the ports **52**, as shown in FIG. **1**. Note that other connection schemes between the TLS sensor and the system console can also be used without limitation. As just described, the magnetic elements **106** are employed in the stylet **100** to enable the position of the catheter distal end **76**A (FIG. **2**) to be observable relative to the TLS sensor **50** placed on the patient's chest. Detection by the TLS sensor **50** of the stylet magnetic elements **106** is graphically displayed on the display **30** of the console **20** during TLS mode. In this way, a clinician placing the catheter is able to generally determine the location of the catheter distal end **76**A within the patient vasculature relative o the TLS sensor **50** and detect when catheter malposition, such as advancement of the catheter along an undesired vein, is occurring.

FIGS. **6** and **7**A-**7**E show examples of icons that can be used by the console display **30** to depict detection of the stylet magnetic elements **106** by the TLS sensor **50**. In particular, FIG. **6** shows an icon **114** that depicts the distal portion of the stylet **100**, including the magnetic elements **106** as detected by the TLS sensor **50** when the magnetic elements are positioned under the TLS sensor. As the stylet distal end **100**B is substantially co-terminal with the distal end **76**A of the catheter **72**, the icon indicates the position and orientation of the catheter distal end. FIGS. **7**A-**7**E show various icons that can be depicted on the on the console display **30** when the magnetic elements **106** of the stylet **100** are not positioned directly under a portion of the TLS sensor **50**, but are nonetheless detected nearby. The icons can include half-icons **114**A and quarter-icons **114**B that are displayed according to the position of the stylet magnetic assembly, i.e., the magnetic elements **106** in the present embodiment, relative to the TLS sensor **50**.

FIGS. **8**A-**8**C depict screenshots taken from the display **30** of the system **10** while in TLS mode, showing how the magnetic assembly of the stylet **100** is depicted. The screenshot **118** of FIG. **8**A shows a representative image **120** of the TLS sensor **50**. Other information is provided on the display screenshot **118**, including a depth scale indicator **124**, status/action indicia **126**, and icons **128** corresponding to the button interface **32** included on the console **20** (FIG. **8**C). Though the icons **128** in the present embodiment are simply indicators to guide the user in identifying the purpose of the corresponding buttons of the button interface **32**, in another embodiment the display can be made touch-sensitive so that the icons themselves can function as button interfaces and can change according to the mode the system is in.

During initial stages of catheter advancement through the patient's vasculature after insertion therein, the distal end **76**A of the catheter **72**, having the stylet distal end **100**B substantially co-terminal therewith, is relatively distant from the TLS sensor **50**. As such, the display screenshot will indicate "no signal," indicating that the magnetic field from the stylet magnetic assembly has not been detected. In FIG. **8**B, the magnetic assembly proximate the stylet distal end **100**B has advanced sufficiently close to the TLS sensor **50** to be detected thereby, though it is not yet under the sensor. This is indicated by the half-icon **114**A shown to the left of the sensor image **120**, representing the stylet magnetic assembly being positioned to the right of the TLS sensor **50** from the perspective of the patient.

In FIG. **8**C, the magnetic assembly proximate the stylet distal end **100**B has advanced under the TLS sensor **50** such that its position and orientation relative thereto is detected by the TLS sensor. This is indicated by the icon **114** on the sensor image **120**. Note that the button icons **128** provide indications of the actions that can be performed by pressing the corresponding buttons of the console button interface **32**. As such, the button icons **128** can change according to which modality the system **10** is in, thus providing flexibility of use for the button interface **32**. Note further that, as the button pad **82** of the probe **40** (FIG. **3**A, **3**B) includes buttons **84** that mimic several of the buttons of the button interface **32**, the button icons **128** on the display **30** provide a guide to the clinician for controlling the system **10** with the probe buttons **84** while remaining in the sterile field. For instance, if the clinician has need to leave TLS mode and return to US (ultrasound) mode, the appropriate control button **84** on the probe button pad **82** can be depressed, and the US mode can be immediately called up, with the display **30** refreshing to accommodate the visual information needed for US functionality, such as that shown in FIG. **4**. This is accomplished without a need for the clinician to reach out of the sterile field.

Reference is now made to FIGS. **9** and **10** in describing the integrated catheter placement system **10** according to another example embodiment. As before, the integrated system **10** includes the console **20**, display **30**, probe **40** for US functionality, and the TLS sensor **50** for tip location functionality as described above. Note that the system **10** depicted in FIGS. **9** and **10** is similar in many respects to the system shown in FIGS. **1** and **2**. As such, only selected differences will be discussed below. The system **10** of FIGS. **9** and **10** includes additional functionality wherein determination of the proximity of the catheter distal tip **76**A relative to a sino-atrial ("SA") or other electrical impulse-emitting node of the heart of the patient **70** can be determined, thus providing enhanced ability to accurately place the catheter distal tip in a desired location proximate the node. Also referred to herein as "ECG" or "ECG-based tip confirmation," this third modality of the system **10** enables detection of ECG signals from the SA node in order to place the catheter distal tip in a desired location within the patient vasculature. Note that the US, TLS, and ECG modalities are seamlessly combined in the present system **10** and can be employed in concert or individually to assist in catheter placement.

FIGS. **9** and **10** show the addition to the system **10** of a stylet **130** configured in accordance with the present embodiment. As an overview, the catheter stylet **130** is removably predisposed within the lumen of the catheter **72** being inserted into the patient **70** via the insertion site **73**. The stylet **130**, in addition to including a magnetic assembly for the magnetically-based TLS modality, includes an ECG sensor assembly proximate its distal end and including a portion that is co-terminal with the distal end of the catheter tip for sensing ECG signals produced by the SA node. In contrast to the previous embodiment, the stylet **130** includes a tether **134** extending from its proximal end that operably connects to the TLS sensor **50**. As will be described in further detail, the stylet tether **134** permits ECG signals

detected by the ECG sensor assembly included on a distal portion of the stylet **130** to be conveyed to the TLS sensor **50** during confirmation of the catheter tip location as part of the ECG signal-based tip confirmation modality. Reference and ground ECG lead/electrode pairs **158** (see FIG. **13**A) attach to the body of the body of the patient **70** and are operably attached to the TLS sensor **50** to enable the system to filter out high level electrical activity unrelated to the electrical activity of the SA node of the heart, thus enabling the ECG-based tip confirmation functionality. Together with the reference and ground signals received from the ECG lead/electrode pairs **158** placed on the patient's skin, the ECG signals sensed by the stylet ECG sensor assembly are received by the TLS sensor **50** positioned on the patient's chest (FIG. **10**). The TLS sensor **50** and/or console processor **22** can process the ECG signal data to produce an electrocardiogram waveform on the display **30**, as will be described. In the case where the TLS sensor **50** processes the ECG signal data, a processor is included therein to perform the intended functionality. If the console **20** processes the ECG signal data, the processor **22**, controller **24**, or other processor can be utilized in the console to process the data.

Thus, as it is advanced through the patient vasculature, the catheter **72** equipped with the stylet **130** as described above can advance under the TLS sensor **50**, which is positioned on the chest of the patient as shown in FIG. **10**. This enables the TLS sensor **50** to detect the position of the magnetic assembly of the stylet **130**, which is substantially co-terminal with the distal tip **76**A of the catheter as located within the patient's vasculature. The detection by the TLS sensor **50** of the stylet magnetic assembly is depicted on the display **30** during ECG mode. The display **30** further depicts during ECG mode an ECG electrocardiogram waveform produced as a result of patient heart's electrical activity as detected by the ECG sensor assembly of the stylet **130**. In greater detail, the ECG electrical activity of the SA node, including the P-wave of the waveform, is detected by the ECG sensor assembly of the stylet (described below) and forwarded to the TLS sensor **50** and console **20**. The ECG electrical activity is then processed for depiction on the display **30**. The clinician placing the catheter can then observe the ECG data to determine optimum placement of the distal tip **76**A of the catheter **72**, such as proximate the SA node in one embodiment. In one embodiment, the console **20** which includes the electronic components, such as the processor **22** (FIG. **9**) necessary to receive and process the signals detected by the stylet ECG sensor assembly. In another embodiment, the TLS sensor **50** can include the necessary electronic components processing the ECG signals.

As already discussed, the display **30** is used to display information to the clinician during the catheter placement procedure. The content of the display **30** changes according to which mode the catheter placement system is in: US, TLS, or ECG. Any of the three modes can be immediately called up to the display **30** by the clinician, and in some cases information from multiple modes, such as TLS and ECG, may be displayed simultaneously. In one embodiment, as before, the mode the system is in may be controlled by the control buttons **84** included on the handheld probe **40**, thus eliminating the need for the clinician to reach out of the sterile field (such as touching the button interface **32** of the console **20**) to change modes. Thus, in the present embodiment the probe **40** is employed to also control some or all ECG-related functionality of the system **10**. Note that the button interface **32** or other input configurations can also be used to control system functionality. Also, in addition to the visual display **30**, aural information, such as beeps, tones, etc., can also be employed by the system to assist the clinician during catheter placement.

Reference is now made to FIGS. **11**-**12**E in describing various details of one embodiment of the stylet **130** that is removably loaded into the catheter **72** and employed during insertion to position the distal tip **76**A of the catheter in a desired location within the patient vasculature. As shown, the stylet **130** as removed from the catheter defines a proximal end **130**A and a distal end **130**B. A connector **132** is included at the proximal stylet end **130**A, and a tether **134** extends distally from the connector and attaches to a handle **136**. A core wire **138** extends distally from the handle **136**. The stylet **130** is pre-loaded within a lumen of the catheter **72** in one embodiment such that the distal end **130**B is substantially flush, or co-terminal, with the catheter opening at the distal end **76**A thereof (FIG. **10**), and such that a proximal portion of the core wire **138**, the handle **136**, and the tether **134** extend proximally from a selected one of the extension tubes **74**B. Note that, though described herein as a stylet, in other embodiments a guidewire or other catheter guiding apparatus could include the principles of the embodiment described herein.

The core wire **138** defines an elongate shape and is composed of a suitable stylet material including stainless steel or a memory material such as, in one embodiment, a nickel and titanium-containing alloy commonly known by the acronym "nitinol." Though not shown here, manufacture of the core wire **138** from nitinol in one embodiment enables the portion of the core wire corresponding to a distal segment of the stylet to have a pre-shaped bent configuration so as to urge the distal portion of the catheter **72** into a similar bent configuration. In other embodiments, the core wire includes no pre-shaping. Further, the nitinol construction lends torqueability to the core wire **138** to enable a distal segment of the stylet **130** to be manipulated while disposed within the lumen of the catheter **72**, which in turn enables the distal portion of the catheter to be navigated through the vasculature during catheter insertion.

The handle **136** is provided to enable insertion/removal of the stylet from the catheter **72**. In embodiments where the stylet core wire **138** is torqueable, the handle **136** further enables the core wire to be rotated within the lumen of the catheter **72**, to assist in navigating the catheter distal portion through the vasculature of the patient **70**.

The handle **136** attaches to a distal end of the tether **134**. In the present embodiment, the tether **134** is a flexible, shielded cable housing one or more conductive wires electrically connected both to the core wire **138**, which acts as the ECG sensor assembly referred to above, and the tether connector **132**. As such, the tether **134** provides a conductive pathway from the distal portion of the core wire **138** through to the tether connector **132** at proximal end **130**A of the stylet **130**. As will be explained, the tether connector **132** is configured for operable connection to the TLS sensor **50** on the patient's chest for assisting in navigation of the catheter distal tip **76**A to a desired location within the patient vasculature.

As seen in FIGS. **12**B-**12**D, a distal portion of the core wire **138** is gradually tapered, or reduced in diameter, distally from a junction point **142**. A sleeve **140** is slid over the reduced-diameter core wire portion. Though of relatively greater diameter here, the sleeve in another embodiment can be sized to substantially match the diameter of the proximal portion of the stylet core wire. The stylet **130** further includes a magnetic assembly disposed proximate the distal end **130**B thereof for use during TLS mode. The magnetic assembly in the illustrated embodiment includes a plurality

of magnetic elements **144** interposed between an outer surface of the reduced-diameter core wire **138** and an inner surface of the sleeve **140** proximate the stylet distal end **130**B. In the present embodiment, the magnetic elements **144** include 20 ferromagnetic magnets of a solid cylindrical shape stacked end-to-end in a manner similar to the stylet **100** of FIG. **2**. In other embodiments, however, the magnetic element(s) may vary from this design in not only shape, but also composition, number, size, magnetic type, and position in the stylet. For example, in one embodiment the plurality of magnets of the magnetic assembly is replaced with an electromagnetic coil that produces a magnetic field for detection by the TLS sensor. These and other variations are therefore contemplated by embodiments of the present invention.

The magnetic elements **144** are employed in the stylet **130** distal portion to enable the position of the stylet distal end **130**B to be observable relative to the TLS sensor **50** placed on the patient's chest. As has been mentioned, the TLS sensor **50** is configured to detect the magnetic field of the magnetic elements **144** as the stylet advances with the catheter **72** through the patient vasculature. In this way, a clinician placing the catheter **72** is able to generally determine the location of the catheter distal end **76**A within the patient vasculature and detect when catheter malposition is occurring, such as advancement of the catheter along an undesired vein, for instance.

The stylet **130** further includes the afore-mentioned ECG sensor assembly, according to one embodiment. The ECG sensor assembly enables the stylet **130**, disposed in a lumen of the catheter **72** during insertion, to be employed in detecting an intra-atrial ECG signal produced by an SA or other node of the patient's heart, thereby allowing for navigation of the distal tip **76**A of the catheter **72** to a predetermined location within the vasculature proximate the patient's heart. Thus, the ECG sensor assembly serves as an aide in confirming proper placement of the catheter distal tip **76**A.

In the embodiment illustrated in FIGS. **11-12**E, the ECG sensor assembly includes a distal portion of the core wire **138** disposed proximate the stylet distal end **130**B. The core wire **138**, being electrically conductive, enables ECG signals to be detected by the distal end thereof and transmitted proximally along the core wire. A conductive material **146**, such as a conductive epoxy, fills a distal portion of the sleeve **140** adjacent the distal termination of the core wire **138** so as to be in conductive communication with the distal end of the core wire. This in turn increases the conductive surface of the distal end **130**B of the stylet **130** so as to improve its ability to detect ECG signals.

Before catheter placement, the stylet **130** is loaded into a lumen of the catheter **72**. Note that the stylet **130** can come preloaded in the catheter lumen from the manufacturer, or loaded into the catheter by the clinician prior to catheter insertion. The stylet **130** is disposed within the catheter lumen such that the distal end **130**B of the stylet **130** is substantially co-terminal with the distal tip **76**A of the catheter **72**, thus placing the distal tips of both the stylet and the catheter in substantial alignment with one another. The co-terminality of the catheter **72** and stylet **130** enables the magnetic assembly to function with the TLS sensor **50** in TLS mode to track the position of the catheter distal tip **76**A as it advances within the patient vasculature, as has been described. Note, however, that for the tip confirmation functionality of the system **10**, the distal end **130**B of the stylet **130** need not be co-terminal with the catheter distal end **76**A. Rather, all that is required is that a conductive path between the vasculature and the ECG sensor assembly, in this case the core wire **138**, be established such that electrical impulses of the SA node or other node of the patient's heart can be detected. This conductive path in one embodiment can include various components including saline solution, blood, etc.

In one embodiment, once the catheter **72** has been introduced into the patient vasculature via the insertion site **73** (FIG. **10**) the TLS mode of the system **10** can be employed as already described to advance the catheter distal tip **76**A toward its intended destination proximate the SA node. Upon approaching the region of the heart, the system **10** can be switched to ECG mode to enable ECG signals emitted by the SA node to be detected. As the stylet-loaded catheter is advanced toward the patient's heart, the electrically conductive ECG sensor assembly, including the distal end of the core wire **138** and the conductive material **146**, begins to detect the electrical impulses produced by the SA node. As such, the ECG sensor assembly serves as an electrode for detecting the ECG signals. The elongate core wire **138** proximal to the core wire distal end serves as a conductive pathway to convey the electrical impulses produced by the SA node and received by the ECG sensor assembly to the tether **134**.

The tether **134** conveys the ECG signals to the TLS sensor **50** temporarily placed on the patient's chest. The tether **134** is operably connected to the TLS sensor **50** via the tether connector **132** or other suitable direct or indirect connective configuration. As described, the ECG signal can then be process and depicted on the system display **30** (FIG. **9**, **10**). Monitoring of the ECG signal received by the TLS sensor **50** and displayed by the display **30** enables a clinician to observe and analyze changes in the signal as the catheter distal tip **76**A advances toward the SA node. When the received ECG signal matches a desired profile, the clinician can determine that the catheter distal tip **76**A has reached a desired position with respect to the SA node. As mentioned, in one embodiment this desired position lies within the lower one-third (⅓rd) portion of the SVC.

The ECG sensor assembly and magnetic assembly can work in concert in assisting a clinician in placing a catheter within the vasculature. Generally, the magnetic assembly of the stylet **130** assists the clinician in generally navigating the vasculature from initial catheter insertion so as to place the distal end **76**A of the catheter **72** in the general region of the patient's heart. The ECG sensor assembly can then be employed to guide the catheter distal end **76**A to the desired location within the SVC by enabling the clinician to observe changes in the ECG signals produced by the heart as the stylet ECG sensor assembly approaches the SA node. Again, once a suitable ECG signal profile is observed, the clinician can determine that the distal ends of both the stylet **130** and the catheter **72** have arrived at the desired location with respect to the patient's heart. Once it has been positioned as desired, the catheter **72** may be secured in place and the stylet **130** removed from the catheter lumen. It is noted here that the stylet may include one of a variety of configurations in addition to what is explicitly described herein. In one embodiment, the stylet can attach directly to the console instead of an indirect attachment via the TLS sensor. In another embodiment, the structure of the stylet **130** that enables its TLS and ECG-related functionalities can be integrated into the catheter structure itself. For instance, the magnetic assembly and/or ECG sensor assembly can, in one embodiment, be incorporated into the wall of the catheter.

FIGS. **13**A-**15** describe various details relating to the passage of ECG signal data from the stylet tether **134** to the

TLS sensor **50** positioned on the patient's chest, according the present embodiment. In particular, this embodiment is concerned with passage of ECG signal data from a sterile field surrounding the catheter **72** and insertion site **73**, which includes the stylet **130** and tether **134**, and a non-sterile field, such as the patient's chest on which the TLS sensor is positioned. Such passage should not disrupt the sterile field so that the sterility thereof is compromised. A sterile drape that is positioned over the patient **70** during the catheter insertion procedure defines the majority of the sterile field: areas above the drape are sterile, while areas below (excluding the insertion site and immediately surrounding region) are non-sterile. As will be seen, the discussion below includes at least a first communication node associated with the stylet **130**, and a second communication node associated with the TLS sensor **50** that operably connect with one another to enable ECG signal data transfer therebetween.

One embodiment addressing the passage of ECG signal data from the sterile field to the non-sterile field without compromising the sterility of the former is depicted in FIGS. **13**A-**15**, which depict a "through-drape" implementation also referred to as a "shark fin" implementation. In particular, FIG. **14**A shows the TLS sensor **50** as described above for placement on the chest of the patient during a catheter insertion procedure. The TLS sensor **50** includes on a top surface thereof a connector base **152** defining a channel **152**A in which are disposed three electrical base contacts **154**. A fin connector **156**, also shown in FIGS. **13**A-**13**D, is sized to be slidingly received by the channel **152**A of the connector base **152**, as shown in FIGS. **14**B and **15**. Two ECG lead/electrode pairs **158** extend from the fin connector **156** for placement on the shoulder and torso or other suitable external locations on the patient body. The drape-piercing tether connector **132** is configured to slidingly mate with a portion of the fin connector **156**, as will be described further below, to complete a conductive pathway from the stylet **120**, through the sterile field to the TLS sensor **50**.

FIGS. **13**A-**13**D show further aspects of the fin connector **156**. In particular, the fin connector **156** defines a lower barrel portion **160** that is sized to be received in the channel **152**A of the connector base **152** (FIGS. **14**B, **15**). A hole **162** surrounded by a centering cone **164** is included on a back end of an upper barrel portion **166**. The upper barrel portion **166** is sized to receive the tether connector **132** of the stylet **130** (FIGS. **14**C, **15**) such that a pin contact **170** extending into a channel **172** of the tether connector **132** (FIG. **15**) is guided by the centering hole until it seats within the hole **162** of the fin connector **156**, thus interconnecting the tether connector with the fin connector. An engagement feature, such as the engagement feature **169** shown in FIGS. **13**C and **13**D, can be included on the fin connector **156** to engage with a corresponding feature on the tether connector **132** to assist with maintaining a mating between the two components.

FIG. **13**D shows that the fin connector **156** includes a plurality of electrical contacts **168**. In the present embodiment, three contacts **168** are included: the two forward-most contact each electrically connecting with a terminal end of one of the ECG leads **158**, and the rear contact extending into axial proximity of the hole **162** so as to electrically connect with the pin contact **170** of the tether connector **132** when the latter is mated with the fin connector **156** (FIG. **15**). A bottom portion of each contact **168** of the fin connector **156** is positioned to electrically connect with a corresponding one of the base contacts **154** of the TLS sensor connector base **152**.

FIG. **14**B shows a first connection stage, wherein the fin connector **156** is removably mated with the TLS sensor connector base **152** by the sliding engagement of the lower barrel portion **160** of the fin connector with the connector base channel **152**A. This engagement electrically connects the connector base contacts **154** with the corresponding fin contacts **168**.

FIG. **14**C shows a second connection stage, wherein the tether connector **132** is removably mated with the fin connector **156** by the sliding engagement of the tether connector channel **172** with the upper barrel portion **166** of the fin connector. This engagement electrically connects the tether connector pin contact **170** with the back contact **168** of the fin connector **156**, as best seen in FIG. **15**. In the present embodiment, the horizontal sliding movement of the tether connector **132** with respect to the fin connector **156** is in the same engagement direction as when the fin connector is slidably mated to the sensor connector base channel **152**A (FIG. **14**B). In one embodiment, one or both of the stylet **130**/tether connector **132** and the fin connector **156** are disposable. Also, the tether connector in one embodiment can be mated to the fin connector after the fin connector has been mated to the TLS sensor, while in another embodiment the tether connector can be first mated to the fin connector through the surgical drape before the fin connector is mated to the TLS sensor.

In the connection scheme shown in FIG. **14**C, the stylet **130** is operably connected to the TLS sensor **50** via the tether connector **132**, thus enabling the ECG sensor assembly of the stylet to communicate ECG signals to the TLS sensor. In addition, the ECG lead/electrode pairs **158** are operably connected to the TLS sensor **50**. In one embodiment, therefore, the tether connector **132** is referred to as a first communication node for the stylet **130**, while the fin connector **156** is referred to as a second communication node for the TLS sensor **50**.

Note that various other connective schemes and structures can be employed to establish operable communication between the stylet and the TLS sensor. For instance, the tether connector can use a slicing contact instead of a pin contact to pierce the drape. Or, the fin connector can be integrally formed with the TLS sensor. These and other configurations are therefore embraced within the scope of embodiments of the present disclosure.

As seen in FIG. **15**, a sterile drape **174** used during catheter placement to establish a sterile field is interposed between the interconnection of the tether connector **132** with the fin connector **156**. As just described, the tether connector **132** includes the pin contact **170** that is configured to pierce the drape **174** when the two components are mated. This piercing forms a small hole, or perforation **175**, in the sterile drape **174** that is occupied by the pin contact **170**, thus minimizing the size of the drape perforation by the pin contact. Moreover, the fit between the tether connector **132** and the fin connector **156** is such that the perforation in sterile drape made by piercing of the pin contact **170** is enclosed by the tether connector channel **172**, thus preserving the sterility of the drape and preventing a breach in the drape that could compromise the sterile field established thereby. The tether connector channel **172** is configured so as to fold the sterile drape **174** down prior to piercing by the pin contact **170** such that the pin contact does not pierce the drape until it is disposed proximate the hole **162** of the fin connector **156**. It is noted here that the tether connector **132** and fin connector **156** are configured so as to facilitate alignment therebetween blindly through the opaque sterile

drape **174**, i.e., via palpation absent visualization by the clinician of both components.

Note further that the fin contacts **168** of the fin connector **156** as shown in FIG. **15** are configured to mate with the sensor base contacts **154** in such a way as to assist in retaining the fin connector in engagement with the sensor base channel **152**A. This in turn reduces the need for additional apparatus to secure the fin connector **156** to the TLS sensor **50**.

FIG. **16** shows a typical ECG waveform **176**, including a P-wave and a QRS complex. Generally, the amplitude of the P-wave varies as a function of distance of the ECG sensor assembly from the SA node, which produces the waveform **176**. A clinician can use this relationship in determining when the catheter tip is properly positioned proximate the heart. For instance, in one implementation the catheter tip is desirably placed within the lower one-third (⅓rd) of the superior vena cava, as has been discussed. The ECG data detected by the ECG sensor assembly of the stylet **130** is used to reproduce waveforms such as the waveform **176**, for depiction on the display **30** of the system **10** during ECG mode.

Reference is now made to FIG. **17** in describing display aspects of ECG signal data on the display **30** when the system **10** is in ECG mode, the third modality described further above, according to one embodiment. The screenshot **178** of the display **30** includes elements of the TLS modality, including a representative image **120** of the TLS sensor **50**, and can the icon **114** corresponding to the position of the distal end of the stylet **130** during transit through the patient vasculature. The screenshot **178** further includes a window **180** in which the current ECG waveform captured by the ECG sensor assembly of the stylet **130** and processed by the system **10** is displayed. The window **180** is continually refreshed as new waveforms are detected.

Window **182** includes a successive depiction of the most recent detected ECG waveforms, and includes a refresh bar **182**A, which moves laterally to refresh the waveforms as they are detected. Window **184**A is used to display a baseline ECG waveform, captured before the ECG sensor assembly is brought into proximity with the SA node, for comparison purposes to assist the clinician in determining when the desired catheter tip location has been achieved. Windows **184**B and **184**C can be filed by user-selected detected ECG waveforms when the user pushes a predetermined button on the probe **40** or the console button interface **32**. The waveforms in the windows **184**B and **184**C remain until overwritten by new waveforms as a result of user selection via button pushes or other input. As in previous modes, the depth scale **124**, status/action indicia **126**, and button icons **128** are included on the display **30**. An integrity indicator **186** is also included on the display **30** to give an indication of whether the ECG lead/electrode pairs **158** are operably connected to the TLS sensor **50**.

As seen above, therefore, the display **30** depicts in one embodiment elements of both the TLS and ECG modalities simultaneously on a single screen, thus offering the clinician ample data to assist in placing the catheter distal tip in a desired position. Note further that in one embodiment a printout of the screenshot or selected ECG or TLS data can be saved, printed, or otherwise preserved by the system **10** to enable documentation of proper catheter placement.

Although the embodiments described herein relate to a particular configuration of a catheter, such as a PICC or CVC, such embodiments are merely exemplary. Accordingly, the principles of the present invention can be extended to catheters of many different configurations and designs.

Embodiments of the invention may be embodied in other specific forms without departing from the spirit of the present disclosure. The described embodiments are to be considered in all respects only as illustrative, not restrictive. The scope of the embodiments is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A catheter placement system for positioning a catheter in a vasculature of a patient using at least two different modalities, comprising:

a console, including a display;

a stylet removably positionable within a lumen of the catheter, the stylet including:

a magnetic assembly configured to produce a magnetic field;

an electrocardiogram (ECG) sensor assembly for detecting ECG signals of a node of a heart of the patient; and

a first connector in communication with the ECG sensor assembly;

a tip location sensor positionable on a chest of the patient, the tip location sensor configured to detect the magnetic field of the magnetic assembly when the catheter is disposed within the vasculature of the patient, the magnetic field providing magnetic field information for locating the magnetic assembly relative to the tip location sensor, the tip location sensor configured to communicate the magnetic field information to the console;

a second connector included with one of the tip location sensor and the console, the second connector configured to connect to the first connector of the stylet to enable the ECG signals detected by the ECG sensor assembly to be communicated to at least one of the tip location sensor and the console; and

an external electrode configured to be placed on an external portion of the patient, the external electrode coupled to the second connector,

wherein the console is configured to receive the magnetic field information and at least one aspect of the ECG signal detected by the ECG sensor assembly, the at least one aspect of the ECG signal indicative of proximity of the ECG sensor assembly to the node, and configured to show a graphical representation of the magnetic assembly and the at least one aspect of the ECG signal, including an ECG waveform, on the display.

2. The system as defined in claim **1**, wherein the console display enables a clinician to ascertain when a distal tip of the catheter is positioned at a predetermined location with respect to the node of the heart.

3. The system as defined in claim **1**, wherein the second connector is included with the tip location sensor, and wherein the first and second connectors are physically connected via a perforation defined in a drape interposed between the stylet and the tip location sensor positioned on the chest of the patient, the physical connection of the first and second connectors producing the perforation in the drape and confining the perforation so as to prevent a compromise of a sterile field of the patient.

4. The system as defined in claim **3**, wherein the ECG sensor assembly includes an electrically conductive core wire of the stylet, the core wire in operable communication with the first connector.

5. The system as defined in claim 4, wherein the core wire includes a distally tapered portion, the core wire extending to a distal end of the stylet.

6. The system as defined in claim 4, wherein the first connector includes a pin contact in operable communication with the core wire, the pin contact disposed in a channel defined in the first connector.

7. The system as defined in claim 6, wherein the second connector is a fin connector included with the tip location sensor, the first connector being slidably attachable to the second connector such that the pin contact of the first connector is placed in operable communication with a contact of the second connector to enable ECG signals to pass from the ECG sensor assembly to the tip location sensor.

8. The system as defined in claim 7, wherein the fin connector is selectively removable from the tip location sensor.

9. The system as defined in claim 8, wherein the tip location sensor includes a channel that slidably receives a barrel portion of the fin connector such that at least one electrical contact of the tip location sensor is placed in operable communication with at least one electrical contact of the fin connector.

10. The system as defined in claim 1, wherein the magnetic assembly includes a plurality of magnetic elements positioned proximate a distal end of the stylet, the stylet disposed in the lumen of the catheter such that the plurality of magnetic elements are substantially proximate a distal tip of the catheter.

11. The system as defined in claim 1, further comprising an ultrasound probe operably connected to the console for ultrasonically imaging a portion of the vasculature prior to introduction of the catheter into the vasculature for depiction on the display.

12. The system as defined in claim 11, wherein the display in a first mode depicts aspects relating to ultrasonically imaging by the ultrasound probe, wherein the display in a second mode depicts aspects relating to detection by the tip location sensor of the magnetic field of the magnetic assembly, wherein the display in a third mode depicts aspects relating to detection by the ECG sensor assembly, and wherein the mode depicted by the display is selected without requiring a clinician to reach out of a sterile field of the patient.

13. The system as defined in claim 12, wherein the display in the third mode displays a current ECG trace of the heart node of the patient.

14. The system as defined in claim 12, wherein the display in the second mode depicts a first icon to indicate a first proximity of the magnetic assembly to the tip location sensor and a second icon to indicate a second proximity of the magnetic assembly to the tip location sensor.

15. The system as defined in claim 1, wherein the stylet and the second connector are disposable after a single use.

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